Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

2,2'-dichloro-4,4'-methylenedianiline use: Industrial use of MOCA as a curing agent / chain extender in cast polyurethane elastomer production

ECHA / RAC / SEAC: AFA-O-0000006645-68-01 / D

Consolidated version

Date: 30 / 11 / 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:	**2,2'-dichloro-4,4'-methylenedianiline (MOCA)**
EC No.:	**202-918-9**
CAS No.:	**101-14-4, 126699-69-2, 142661-36-7, 29371-14-0, 51065-07-7, 78642-65-6**

for the following use:

Industrial use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production

Intrinsic property referred to in Annex XIV:

Article 57 (a) of the REACH Regulation

Applicant:

REACHLaw Ltd in its legal capacity as Only Representative of Suzhou Xiangyuan Special Fine Chemical Co., Ltd

Reference number:

11-2120134434-64-0000

Rapporteur, appointed by the RAC:	**Tiina SANTONEN**
Rapporteur, appointed by the SEAC:	**Simone FANKHAUSER**
Co-rapporteur, appointed by the SEAC:	**Karine FIORE-TARDIEU**

PROCESS FOR ADOPTION OF THE OPINIONS

On **17/05/2016 REACHLaw Ltd in its legal capacity as Only Representative of Suzhou Xiangyuan Special Fine Chemical Co., Ltd** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **11/11/2016** 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 https://echa.europa.eu/applications-for-authorisation-consultation on **09/11/2016**. Interested parties were invited to submit comments and contributions by **09/01/2017**.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation as well as the responses of the applicant.

The draft opinions of RAC and SEAC take into account the responses of the applicant as well as third parties 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 **24/07/2017**.

The applicant informed on **26/07/2017** that it wished to comment the draft opinions of RAC and SEAC according to Article 64(5) and sent his written argumentation to the Agency on **02/10/2017**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health 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 **09/06/2017**.

The draft opinion of RAC was agreed by **consensus**.

The opinion of RAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of RAC was adopted by consensus on **30/11/2017**.

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 **15/06/2017**.

The draft opinion of SEAC was agreed by **consensus**.

The opinion of SEAC

Based on the aforementioned draft opinion and taking into account written argumentation received from the applicant, the opinion of SEAC was adopted by consensus on **30/11/2017**.

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 carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

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

RAC confirmed that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements are expected to improve the situation.

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 carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

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

SEAC considered that the applicant's assessment of: (a) the potential socioeconomic benefits of the use, (b) the potential adverse effects to human health 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, provided that the suggested conditions and monitoring arrangements are adhered to.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Description for additional conditions and monitoring arrangements for the authorisation:

The applicant shall apply following requirements for the management of exposure to MOCA. These requirements shall be communicated to downstream users in exposure scenarios for use of MOCA pellets.

Automatic moulding process:

1. Automation and containment of the moulding process, including a glove box for the loading of MOCA, automatic transfer of MOCA to the reactor and an enclosed system for the melting and mixing phase can be considered to represent good practice and whenever practicable shall be adopted.
2. All of the aforementioned exposure control/containment measures shall be fitted with extraction ventilation (LEV), unless it can be shown (by measurements) that emissions to the air are negligible.
3. Similarly, LEV shall be used in connection with subsequent loading and sampling as well as the dispensing and moulding phases. Curing ovens shall be equipped with extraction.
4. Regular maintenance program of the mechanical extraction ventilation system shall be implemented, including frequent checking of air velocity by e.g. smoke tube and annual throughout testing of the effective and correct function of the system.
5. A regular cleaning and maintenance program of the glove box, including the structural integrity of the gloves, shall be implemented, to eliminate the potential for dermal exposure.
6. Appropriate working clothing (with long sleeves) and chemical resistant gloves shall be used in all tasks involving the use of MOCA, including the loading phase. In maintenance or cleaning of large spills, full body Personal Protective Equipment (PPE), e.g. Tyvek, should be worn.

Manual moulding process (covering 11% of the use according to the applicant):

7. In manual moulding, LEV (e.g. partially enclosed extraction booth or fume cupboard) shall be applied when MOCA pellets are loaded from the drums to the melter. Melting shall be done in an enclosed system with extraction. The mixing step shall include LEV, and it shall be done using automatic stirrer to prevent close contact and exposure of worker due to splashes.
8. Regular maintenance program of the mechanical extraction ventilation system shall be implemented, including frequent checking of air velocity by e.g. smoke tube and annual throughout testing of the effective and correct function of the system.
9. The dispensing and moulding phases and curing ovens shall be equipped with local extraction.
10. Appropriate working clothing (jacket with long sleeves or coveralls) and inner chemical (MOCA) resistant gloves together with outer (e.g. heat resistant) gloves shall be used in all tasks involving the use of MOCA. In maintenance or cleaning of large spills, full body PPE, e.g. Tyvek, should be worn.
11. When MOCA is moved from one place to another (WCS2; moving melted MOCA to mixing area) closed containers shall be always used.

Training and general housekeeping practises (both automatic and manual process):

12. Workers shall be regularly (at least yearly) trained in the proper use of PPE, including the frequency of changing gloves, the correct removal of contaminated gloves and proper storage of gloves and Respiratory Protective Equipment (RPE), as well as fit-testing and maintenance of RPE. RPE shall be used as described in the relevant WCSs of the application. Appropriate supervision shall be provided to ensure availability, correct use and maintenance of all PPE.
13. Procedures that would address good housekeeping shall be implemented by all users of MOCA. Any spillages of MOCA or PU mixture shall be cleaned immediately using appropriate cleaning methods. Following each batch, cleaning of work surfaces, which may contain traces of MOCA, shall be performed to prevent build-up of MOCA. Also, other general good industrial hygiene practices shall be applied, including the prevention of the areas in which MOCA is used should be strictly segregated from other activities and the access limited to trained personnel. Training and supervision shall be provided to ensure adherence to all procedures.
14. Any containers of MOCA shall be closed and stored in a designated area suitable for the storage of dangerous chemicals.

Monitoring activities (both automatic and manual moulding)

15. Exposure of all workers working within the premises in which MOCA is used shall be followed by regular, biannual (twice per year) biomonitoring campaigns, in which total urinary MOCA levels are measured. If urinary levels are repeatedly low (below LOD), frequency of monitoring may be reduced.
16. Measurement of surface contamination shall be conducted in order to prevent exposure via the contaminated surfaces. This is especially important when biomonitoring shows measurable (above LOD) urinary MOCA levels.
17. The information gathered in the monitoring campaigns shall be used by the applicant to review and improve the risk management measures (RMMs) and operational conditions (OCs) to further reduce workers' exposure to MOCA. The outcomes and conclusions of this review, including those related to the implementation of any additional RMMs, must be documented. The results of the monitoring and of the review of the OCs and RMMs shall be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted.
18. Wipe and powdering tests of representative samples (i.e. dependent on the production volume) of end-products shall be performed to ensure that the levels of MOCA in the final product are below classification concentration cut-off limit 0.1% w/w.

Prevention of environmental emissions:

19. Regarding environmental emissions, LEV filters/scrubbers shall be used to minimize air emissions. In order to prevent any waste water releases washing of empty containers shall be prohibited.

AND

Conditions for the review report

In case the applicant submits a review report or Downstream Users submit further authorisation applications, a more precise name and description of the use applied for, and a more specific (narrow) scope of the use applied for is requested in terms of the different articles/parts manufactured.

REVIEW

Taking into account the information provided in the application for authorisation prepared by the applicant and the comments received on the broad information on use, the duration of the review period for the use is recommended to be **4 (four) 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):

2. Is the substance a threshold substance?

☐ YES

☒ NO

Justification:

2,2'-dichloro-4,4'-methylenedianiline (MOCA) has a harmonised classification as Carc. 1B (H350) according to CLP.

Based on studies which show its carcinogenic potential, the Risk Assessment Committee (RAC) has concluded that MOCA 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/32/2015/10 rev 1).

3. Hazard assessment. Are appropriate reference values used?

Justification:

RAC has established a reference dose response relationship for the carcinogenicity of MOCA (RAC/32/2015/10 rev 1), which was used by the applicant. MOCA has caused lung tumours in animal tests when exposed daily via the oral route. Data on the carcinogenicity in humans was limited and not suitable for deriving dose-responses. The dose-response relationship for carcinogenicity was derived by linear extrapolation from oral studies in rats, which can be considered to result in a conservative estimate of risks especially at low exposure levels.

Table 1: Dose-response relationship for carcinogenicity of MOCA established by RAC (RAC/32/2015/10 rev 1)

Route of exposure	Population	Cancer risk for 1 unit
Inhalation	Workers	9.65×10^{-6} per µg/m³
	General population	5.43×10^{-5} per µg/m³
Dermal	Workers	3.38×10^{-5} per µg/kg bw/day
Oral	General population	9.43×10^{-5} per µg/kg bw/day

RAC considers that when biomonitoring data are available, these can be used to estimate cancer risks for occupational exposure.

Since 1 µg/m³ exposure (which corresponds to a daily dose of 10 µg in occupational exposure) represents a cancer risk of 9.65×10^{-6},

5 µmol/mol creatinine in a Friday afternoon sample (corresponding to a daily dose of 17 µg) corresponds to a risk of 16.4×10^{-6} and

0.5 µmol/mol creatinine (detection limit of current analytical techniques) corresponds to cancer risk of 1.64×10^{-6}.

Acknowledging that the calculations to estimate daily dose are not precise and include some assumptions, in RAC's opinion biomonitoring is currently the best method to estimate the total exposure to MOCA in occupational settings.

Are all appropriate and relevant endpoints addressed in the application?

The endpoint identified in the Annex XIV entry is 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.

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

Description:

Short description of the use

MOCA is manufactured outside the EU but is imported for use as a chain extender/curing agent in the production of hot cast polyurethane elastomers, to achieve certain physical properties in the finished articles, like high abrasion/tear resistance and corrosion resistance. It is used in the production of many types of articles such as industrial rollers, wheels, conveyor belting, shock absorption pads and mining equipment.

The applicant has excluded professional uses of MOCA (e.g. as hardener in arts and construction) from the scope of the submitted application. Article service life or consumer exposure are not considered to be relevant by the applicant, because during the hot moulding process MOCA reacts rapidly with the pre-polymer and is consumed in the process, leaving virtually no free MOCA in the fully cured article. The amount of MOCA left in the product is, according to the applicant, less than 0.1%.

Total tonnage of use is 516 tonnes. It is estimated that MOCA is used at 89 sites in the European Union. The estimated number of exposed workers is 213. The use includes one environmental exposure scenario and two worker exposure scenarios. Worker exposure scenarios are as follows:

IW-1: Use as curing agent/chain extender in manual polyurethane casting process

IW-2: Use as curing agent/chain extender in automated polyurethane casting process

The use of MOCA as curing agent includes following process steps:

- The transfer of MOCA pellets from the drums to smaller containers. In the case of manual moulding - this is performed by scooping or by manual moving the pellets to

a hopper. In the case of automatic process, MOCA drums are placed inside the glove box and opened there.

- In the automatic process, loading of MOCA is done from the glove box and pellets are fed to a reactor by vacuum transfer or gravity feed. In the reactor, MOCA is melted at ca 120°C and then automatically transferred to mixing head to form PU mix in a closed system.
- In the manual process, MOCA pellets are transferred manually to the melter and thereafter molten MOCA is mixed with the prepolymer (diisocyanates) to form PU mixture. . Weighing of MOCA pellets can be done before or after melting.
- Ready PU mix is dispensed straight to moulds or to closed containers for later use; the same (open) technique is used in automated and manual processes.
- The process includes sampling of MOCA for quality control (manual sampling, e.g. by scooping of small amounts of pure MOCA) and cleaning and maintenance activities, including waste management and e.g. filter changes.

Contributing scenarios related to exposure scenarios are listed in Table 2. The use of MOCA in automated polyurethane casting process (IW-2) is more common; according to the applicant only 11% of the total tonnage is used in manual process and the rest in the automated process.

Table 2: Contributing Scenarios presented in the Use

Contributing scenario	ERC / PROC	Name of the scenario
ECS1	ERC 6d	Use as curing agent/chain extender in polyurethane moulding process
IW-1: WCS 1	PROC 8a	Transfer of MOCA pellets from the drums to smaller containers
IW-1: WCS 2	PROC 5	Melting and mixing of MOCA in polyurethane casting process
IW-1: WCS 3	PROC 4	Dispensing and casting (including curing and demoulding) of polyurethane mixture containing MOCA
IW-1: WCS 4	PROC 8a	Maintenance and cleaning activities
IW-1: WCS 5	PROC 8a	Sampling
IW-2: WCS 1	PROC 5	Melting and mixing of MOCA in polyurethane casting process
IW-2: WCS 2	PROC 4	Dispensing and casting (including curing and demoulding) of polyurethane mixture containing MOCA
IW-2: WCS 3	PROC 8a	Maintenance and cleaning activities
IW-2: WCS 4	PROC 8a	Sampling

Workers exposure

Exposure estimation methodology:

To obtain information needed to perform exposure assessment, the applicant has collected information on exposure measurements, operating conditions (OCs) and risk management measures (RMMs) through a questionnaire sent to moulders and distributors. According to the applicant, companies representing altogether 65% of the tonnage responded to the questionnaire. Regarding exposure data, 17 out of 23 companies reported that they had performed biomonitoring whereas 6 companies reported not to conduct biomonitoring. Relevant biomonitoring data were, however, received only from 9 companies. Although 60% of the responders reported to have conducted air monitoring, air measurement results were received only from 5 companies. One company reported results from surface samplings to detect surface contamination in the workbench in the mixing area. To complement the reported measurements, the applicant performed inhalation exposure modelling using ART 1.5 or in the case of dermal exposure RISKOFDERM. Parameters used in modelling were described in CSR. Four of the six companies reporting results from air/surface monitoring were the same reporting biomonitoring data.

Inhalation:

Results of the air measurements were reported from 5 sites, all companies except one performing machine moulding (automatic process). The reported levels were low; for both personal and static samplings the levels stayed mostly below LoDs (reported LoDs varied from < 1 µg/m^3 to 32 µg/m^3, in one case LOD was not given. In the manual moulder, the reported levels were 0.22-1.32 µg/m^3. One company performing machine moulding had specified that the measurements were related to moulding, the levels being in all these cases below LoDs (LoD 20-32 µg/m^3). In other cases, the data provided by the applicant did not clearly specify the activities covered by air sampling. Therefore, the interpretation and the use of the air measurement data provided by the applicant is difficult. Low air levels were, however, supported by modelled data, which was provided as corroborating information. The modelled values are given in Table 3. Also, literature data support low air emissions, for example, according to the study by Cocker et al (Ann Occup Hyg, 53, 499-507, 2009), only 16% of personal samples were above LoD (1 µg/m^3) with a maximum level of 11 µg/m^3 and 90th percentile <1 µg/m^3. Highest levels were detected when mixed liquid PU was poured into moulds without any LEV. Also static samples showed low MOCA air levels (9% > LoD, highest level 11 µg/m^3, 90th percentile < 1 µg/m^3) although the samplers were placed around melting, mixing, and casting, where concentrations were thought to be highest.

Dermal:

Besides biomonitoring data providing information on the combined exposure to MOCA, modelled data on dermal exposure were provided as supporting information (not used in risk characterization). Modelling was performed by using RISKOFDERM; the results are presented in Table 2. Parameters used for the modelling were provided by the applicant. Effectiveness of 95% was assumed for the protective gloves. As can be seen in Table 2, in the case of manual moulding, in WCS1 and WCS2, dermal exposures of 13.07 and 14.5 µg/kg bw were predicted by the model. This can be calculated to correspond to a daily intake of 455 and 508 µg/day, respectively, when assuming 50% bioavailability via dermal route. Thus, the corresponding urinary levels resulting solely from dermal exposure in WCS 1 and 2 can be calculated to be 134 and 149 µmol/mol creatinine, respectively (i.e. combined urinary levels for these two WCSs would be almost 300 µmol/mol creatinine). When

comparing these values to available biomonitoring data (which takes into account exposure via all exposure routes), it is evident that dermal modelling is likely to overestimate the skin exposure. Overestimation is partly due to the conservative estimate of 50% bioavailability via the dermal route.

One company provided data on surface sampling; MOCA contamination in the workbench in the mixing area was reported to be 0.05 µg/cm^2.

Table 3: Modelled data on exposure – dermal and inhalation. IW-1 refers to ES1 (manual moulding), IW-2 to ES2 (automatic moulding)

Contributing scenario	Route of exposure	Method of assessment	Exposure value*
IW-1: WCS 1	Inhalation	ART 1.5	8 µg/m³
	Dermal	RiskofDerm	13.07 µg/kg bw
IW-1: WCS 2	Inhalation	ART 1.5	0.85 µg/m³
	Dermal	RiskofDerm	14.5 µg/kg bw
IW-1: WCS 3	Inhalation	ART 1.5	0.012 µg/m³
	Dermal	RiskofDerm	0.0598 µg/kg bw
IW-1: WCS 4	Inhalation	ART 1.5	7.5 µg/m³
	Dermal	RiskofDerm	1.53 µg/kg bw
IW-1: WCS 5	Inhalation	ART 1.5	0.0185 µg/m³
	Dermal	RiskofDerm	0.045 µg/kg bw
IW-2: WCS 1	Inhalation	ART 1.5	0.005 µg/m³
	Dermal	RiskofDerm	0.1307 µg/kg bw
IW-2: WCS 2	Inhalation	ART 1.5	0.012 µg/m³
	Dermal	RiskofDerm	0.0598 µg/kg bw
IW-2: WCS 3	Inhalation	ART 1.5	7.5 µg/m³
	Dermal	RiskofDerm	1.53 µg/kg bw
IW-2: WCS 4	Inhalation	ART 1.5	0.0185 µg/m³
	Dermal	RiskofDerm	0.045 µg/kg bw

**Takes into account the duration of the task and the PPE used*

Biomonitoring:

Taking into account the low vapour pressure of MOCA and the high skin permeation, biomonitoring is generally considered as the best method to assess occupational exposure. The relevant method is to measure total MOCA (free and conjugated) in urine after heat or acid hydrolysis. The results are usually expressed as µmol/L or µmol/mol creatinine (to correct for urinary creatinine excretion). Detection limits vary between 3.7 – 5 nmol/L (1 - 1.5 µg/L), corresponding approximately to 0.35 - 0.5 µmol/mol creatinine (SCOEL, 2010/2013). In workers not exposed to MOCA, urinary levels are below the detection limits of these modern analytical techniques (RAC/32/2015/10 rev 1). According to the survey made by the applicant, 17 companies out of 23 reported to conduct biomonitoring. The biomonitoring results were received from 11 companies. Data originated from companies based in UK, France, Netherlands, Greece and Ireland. Data from two Italian companies were also included in these 11 datasets, but the relevance of these data is questionable,

because it is unsure what has been measured and the result is given as “zero” or “-” without information on the detection limit. Therefore, only data provided by nine companies was considered to be relevant. Three of these nine companies represented manual moulders. Some information on RMMs related to the tasks covered by biomonitoring were provided during the review process. Although data were also available from preceding years from some companies, for the exposure assessment the applicant used data from 2014 (except one dataset was from 2013). These data are compiled in Table 4. Biomonitoring is considered to reflect exposure resulting from all daily activities. According to the applicant, the companies using MOCA have usually only few workers who are performing all relevant tasks.

Table 4. Biomonitoring data from 9 companies relevant for the exposure assessment. Levels are presented as µmol/mol creatinine

Company ID	Automated/ Manual	No of samples/ employees tested	Maximum level	Median	90th percentile
a	Automated	13	23	< 4	-
b*	Automated/ Manual	10	3.8	0.95	3.02
c	Automated	13	2.1	0.3	1.2
d	Automated	10	19.6	10.3	-
h	Automated	20	6	1.78	3.6
i	Automated/ Manual	15	10.4	4.4	7.1
j	Manual	2	-	1.2	-
k	Manual	4	13.3	6	8.8
l	Manual	16 x 2	3.8	nd	-

*data are from year 2013, and not determined

In addition to the data collected from the companies by questionnaire, the applicant referred also to literature data, which is available from UK and from France. These are used as supporting information in exposure assessment. These data include following studies (for full references, see annex 1):

- A study by Cocker et al 1996 (UK) describes a decline in the exposure to MOCA in polyurethane manufacturing from 180 µmol/mol creatinine (90th percentile) in 1977 to 15 µmol/mol creatinine in 1993–1994.
- Robert et al., 1999 (Fr), report a geometric mean of 12.8 µg/L among polyurethane workers, with a range of 0.5–570 µg/L. Generally levels were reported to be below 20 µg/L, which corresponds ~7 µmol/mol creatinine.
- According to Cocker et al 2009, the 90th percentile of all the urinary MOCA levels was 8.6 µmol/mol creatinine (with a maximum value of 25 µmol/mol creatinine). The

study included 25 SMEs of which 15 were using manual methods for polyurethane manufacturing. This study also reports the results of the follow-up of urinary MOCA levels in UK, showing the decline of 90th percentiles from ~30 µmol/mol creatinine in 1986 to the level of ~10 µmol/mol creatinine in 1996.

- The study by Keen et al., 2012, is a follow-up study to Cocker et al. (2009). In this study, median urinary levels among polyurethane workers were 1.4 µmol/mol creatinine and the 90th percentile was 10 µmol/mol creatinine. 170 out of 446 samples were below LOD 0.4 µmol/mol creatinine.

RMMs applied

Table 5: Operational Conditions and Risk Management Measures

Contributing scenario	PROC	Duration of exposure	LEV used	RPE used + effectiveness	Skin protection+ effectiveness	Other RMMs
IW-1: WCS 1	PROC 8a	5-20 min	+/-*	FFP2/3 or half-masks P2/3 (APF 20)	Chemical resistant gloves (EN 374) (95%)	Basic general ventilation (1-3 air changes/hour)
IW-1: WCS 2	PROC 5	5-10 min	+/-*	FFP2/3 or half-masks P2/3 (APF 20)	Chemical resistant gloves (EN 374) (95%)	Basic general ventilation (1-3 air changes/hour)
IW-1: WCS 3	PROC 4	1-20 min	+/-*	-	Chemical resistant gloves (EN 374) (95%)	Basic general ventilation (1-3 air changes/hour)
IW-1: WCS 4	PROC 8a	1-60 min	-	FFP2/3 or half-masks P2/3 (APF 20)	Chemical resistant gloves (EN 374) (95%)	Basic general ventilation (1-3 air changes/hour)
IW-1: WCS 5	PROC 8a	5 min	-	half-masks with P3 filters (APF 20)	Chemical resistant gloves (EN 374) (95%)	Basic general ventilation (1-3 air changes/hour)
IW-2: WCS 1	PROC 2	5-60 min	+/-*	FFP2/3 or half-masks P2/3 (APF 20)	Chemical resistant gloves (EN 374) (95%)	Glovebox (enclosed system) and basic general ventilation (1-3 air changes/hour)
IW-2: WCS 2	PROC 4	1-20 min	+/-*	-	Chemical resistant gloves (EN 374) (95%)	Basic general ventilation (1-3 air changes/hour)
IW-2: WCS 3	PROC 8a	1-60 min & variable frequency	-	FFP2/3 or half-masks P2/3 (APF 20)	Chemical resistant gloves (EN 374) (95%)	Basic general ventilation (1-3 air changes/hour)
IW-2: WCS 4	PROC 8a	5 min	-	half-masks with P3 filters (APF 20)	Chemical resistant gloves (EN 374) (95%)	Basic general ventilation (1-3 air changes/hour)

*+/- Since the applicant was not sure if LEVs are used in all places, a worst case scenario - LEV not used - was considered in the application; all modelling was performed not considering LEV.

Other Risk management measures used to control exposure:

MOCA is imported only in the form of pellets, this reduces the dustiness when compared to the use in powder form.

Some companies perform surface wipe testing in order to identify MOCA contamination in working areas. Some companies have detailed instructions for the safe handling of MOCA which follow e.g. the guidance developed by UK HSE on the safe handling of MOCA.

In RAC's opinion, general good-housekeeping practices are extremely important to reduce the potential for exposure resulting from handling MOCA; for example frequent cleaning should be conducted in order to prevent MOCA build-up around working areas. Regular training of workers in good industrial hygiene practices and in the proper use of personal protective equipment is also important.

Discussion of the exposure information:

The applicant has based its risk assessment and characterisation on biological monitoring, providing also some measured and modelled inhalation exposure data, and modelled dermal exposure estimations. Since MOCA has a low vapour pressure (<0.001 Pa at 20°C) and high potential for skin permeation, biomonitoring is generally considered as the best method to assess occupational exposure to MOCA: a high contribution via dermal exposure is expected. In addition, hand-to-mouth exposure at workplaces may represent an important route of exposure for a substance with this profile and the biomonitoring is the only way to measure combined exposure via all these routes. The biomonitoring dataset submitted by the applicant is very limited, especially in the case of manual moulding. However, there are literature data supporting the applicant's assessment. These data show that both in manual and automatic moulding exposure can be minimised to a level at or below 10 µmol/mol creatinine as urinary levels and if best industrial hygiene practices are followed even well below these levels.

Modelled exposure data show significantly higher exposures compared to biomonitoring data, especially in the case of manual moulding. These high levels come mainly from modelled dermal exposure for WCS 1 and 2. Since even older biomonitoring data presented in the literature (from the 1980's and 1990's) do not support these modelled values, modelled exposure (combined with a conservative estimate of 50% dermal absorption) is considered to overestimate. However, it should be noted that inappropriate handling of MOCA may result in higher exposure than shown by the biomonitoring data submitted by the applicant or the most recent literature. Exposure scenarios presented by the applicant include also so-called "worst case scenarios", which include e.g. transfer, melting and mixing of MOCA manually without LEV or any containment. According to the data provided by the applicant, all of the manual moulders providing biomonitoring data had LEV in place in these process steps. Therefore, RAC is of the opinion that these types of inferiorpractices are not covered by the measured data provided by the applicant. Thus, although the biomonitoring approach selected by the applicant is considered to be the best approach to assess the exposure, inclusion of these "worst case" practices, which are not substantiated by biomonitoring data, creates the main uncertainty in the applicant's assessment.

Combined exposure

The applicant used biomonitoring data for the assessment of combined exposure. It takes into account all exposure routes including inhalation, dermal and hand-to-mouth exposure and the use of personal protective equipment. Biomonitoring also represents the full shift exposure, resulting from all tasks performed.

The 90th percentile value - 8.8 µmol/mol creatinine - was used for manual moulding and the median value of 10.3 µmol/mol creatinine was used for automatic moulding. The median value was selected, since in most of the cases there were no data on 90th percentiles and the only reported 90th percentiles for automatic moulding were lower than the median value of 10.3 µmol/mol creatinine measured in one company. Lower exposure levels in manual moulding (which in reality has the potential for higher exposure due to manual tasks), could be due to a number of factors, for example, the more limited number of available measurements, different volumes of MOCA handled during the day by manual and automatic moulders, etc. These two values (for manual or automatic moulding) can be rounded to **10 µmol/mol creatinine**, which is the 90th percentile observed in the study by Keen et al., 2012, including both manual and automatic moulding. RAC therefore used the value of 10 µmol/mol creatinine for further analysis of both ES1 and ES2. This approach will also avoid giving the wrong impression that manual moulding is likely to result in lower exposure than automatic moulding, if similar volumes of MOCA are used.

Uncertainties related to the exposure assessment:

The exposure assessment is based on the biomonitoring data; relevant data are, however, only available from 9/89 sites. Of these, only three sites represent manual moulders. On the other hand, there are literature data supporting the exposure estimate provided by the applicant. Although this reduces uncertainty related to the exposure estimates, it should be noted that this literature data comes mainly from UK where the management of exposure to MOCA has been in the focus of UK HSE for several decades. Thus, the representativeness of this data across the EU is uncertain. The main uncertainty is, however, related to the fact that OCs and RMMs, as described in the application, include a wide variety of practices and also practices which are not substantiated with measurement data. The “worst case practices” described by the applicant may result in higher exposures than estimated on the basis of measured data.

One smaller uncertainty is related to exposure in maintenance and cleaning activities. It is not known how well available biomonitoring data reflects exposure in maintenance and cleaning activities, especially infrequent maintenance, with possible higher exposure potential. The applicant provided modelled data for maintenance activities, which were considered to represent highest exposure, i.e. cleaning of MOCA spills or changing of very contaminated filters. Total systemic exposure calculated by RAC from the exposure levels predicted by the models for cleaning and maintenance activities is ~4 times higher than exposure estimates based on biomonitoring analyses. It should however, be noted that changing of very contaminated filters or cleaning of large spills are not likely to occur daily. Biomonitoring data, on the other hand, is likely to reflect daily cleaning activities.

The application does not include an assessment of consumer or professional end-user exposure, because of the low (generally well below 0.1%) levels of unreacted MOCA in the end-products. Some companies (but not all) perform wipe and powdering tests to confirm the low levels of unreacted MOCA in their products. However, this is not done by all the

companies, and in some circumstances, the levels may be close to 0.1%. During the trialogue, the possibility of exceeding 0.1% was brought up by a third party. This can be considered as one additional uncertainty related to the applicant's assessment.

The overall level of uncertainty related to how well the available biomonitoring data, used for risk characterisation, represents the exposure situations and its representativeness in relation to RMMs and OCs given in WCSs, is considered to be significant. **Since this uncertainty is mostly related to the variable practices described in WCSs, it is possible to reduce such uncertainty significantly by applying strict conditions and additional monitoring arrangements, which will define the minimum standards needed to minimize exposure at (and below) the levels used for risk characterisation.**

Environmental releases / Indirect exposure to humans via the environment

Exposure of MvE (local/regional) was assessed by modelling. ERC 6d was used as a starting point. ERC 6d is recommended for cases in which reactive process regulators are used in polymerization process. RAC considers the selection of ERC is appropriate.

Default, ERC 6d based release factor of 0.005% was used for waste water releases. According to the applicant, there are no releases to the waste water directly from the process but 0.005% was used as a worst case estimate to cover also situations in which empty containers are rinsed / washed and waste water contain traces of MOCA.

For air releases, the applicant used the release factor of 0.005% which comes from the OECD Emission Scenarios for Plastic Additives (2009) for liquid curing agents for compounding activity. For solid curing agents, an emission factor of 0% was recommended by the OECD (2009), but since MOCA is melted - emission factor for liquids was considered more appropriate. Since MOCA is not volatile, the applicant considered this as a more appropriate estimate of the air releases than the ERC 6d based default value of 35%. One company reported negligible releases to air (below LoD – however, no information on the value of LoD was provided). This company had LEV filters in place. According to the applicant's survey, 33% of survey respondents had filters/scrubbers for exhausted air.

For releases to soil, a release factor of 0% was used, since there are no releases to soil from the use of MOCA.

RMMs applied

Water is not used in the process. However, according to the survey performed by the applicant some of the companies perform washing of the empty containers, which may result in waste water releases. Waste coming from the process (including contaminated filters, PPE, clothing, and empty containers) is treated as hazardous waste. 33% of the companies replying to the applicant's survey had LEV filters/scrubbers in place to prevent air emissions. However, no information on their effectiveness is provided. Low vapour pressure of MOCA is considered to limit air releases.

Table 6: Summary of environmental emissions

Release route	Release factor	Release estimation method and details
Water	0.005%	Default factor based on ERC 6d
Air	0.005%	Based on OECD Emission Scenarios for Plastic Additives (2009) for liquid curing agents for compounding activity
Soil	0%	No soil releases from this use.

Human exposure via the air or food and water was estimated using EUSES. The applicant states that MOCA has potential to bioaccumulate in aquatic species and in the food chain (EPA 1994). MOCA has potential for bioaccumulation on plants, but translocation within the plant is limited to roots. However, as MOCA is not easily removed from the plant surface by washing, exposure also from above ground parts of plants are possible. (EPA 1994). Therefore the man via the environment exposure was calculated for the whole food basket as the worst case scenario.

Local and regional PECs are summarised in Table 7.

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: 2.29×10^{-7} mg/m³ Regional PEC: 8.08×10^{-11} mg/m³
Man via Environment - Oral	Exposure via food consumption: Local: 1.16×10^{-5} mg/kg/day Regional: 1.35×10^{-8} mg/kg/day

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

The assessment of MvE is based on modelling. There is virtually no measured data on air or waste water releases. One company reported negligible (below LOD) releases to air. This company had LEV filters in place. According to the applicant's survey, only 33% of survey respondents had LEV filters/scrubbers. If these are in place, releases can be considered minimal. Although it is recognized that MOCA has a low vapour pressure even when melted, it is difficult to conclude on the conservativeness of the release factor of 0.005% to air in cases in which LEV filters/scrubbers are not used, since there is no measured data.

It is uncertain if some companies wash empty containers resulting in releases to waste water. Containers include a plastic bag inside and according to the distributor the drum itself is not washable. If they are not washed, waste water releases can be considered negligible and 0.005% waste water releases as a worst case scenario, since the process itself is not in contact with water.

Overall, although there are some uncertainties related to the environmental exposure assessment, these are not considered significant and can be addressed by additional conditions.

Conclusion

RAC considers that:

- The description of use allows conclusions to be drawn related to exposure situations.
- Biomonitoring is recognised by RAC as the best way to assess the occupational exposure to MOCA, and was used by the applicant.
- The exposure assessment is, however, based on a limited exposure data set and although there are literature data to support the applicant's assessment, uncertainties related to the representativeness of the data remain, in relation to both the number and geographical spread of companies, and the RMMs and tasks represented by the data.
- The main uncertainty is associated with risk characterisation and human health impact assessment and the fact that worker exposure scenarios include a wide range of practices, which do not, in all cases, represent best industrial hygiene practices, and are not substantiated by the exposure data.
- The assessment of MvE is based on modelled data and virtually no measured data were presented. There are some uncertainties related to the applicant's assessment but these are not considered to compromise the use of data in the health impact assessment.

Despite the uncertainties mentioned above, RAC considers on balance that the worker and general population exposure assessment can be used for risk characterisation and human health impact assessment.

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

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

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

The operating conditions and risk management measures (RMMs) described in the application include a wide variety of practices. The practices described as "worst case scenarios" are not considered to represent good occupational hygiene practices in the field.

The application includes separate exposure scenarios for automatic and manual moulding. In automatic moulding, as opposed to manual moulding, loading of MOCA occurs in a glovebox and the melting and mixing phases are performed in an enclosed reactor. The subsequent moulding and curing phases are not closed (regardless of whether the process is automatic or manual), but typically include the use of LEVs. Any minimum effectiveness of the LEVs has not been specified by the applicant. In addition, protective clothing (including chemical resistant gloves) and RPE (full face or half mask) with P3 filters are described to be used.

Automation and containment of the moulding process, including a glove box for the loading of MOCA, automatic transfer of MOCA to the reactor and enclosed systems for melting and mixing phase can be considered to represent good practice and shall be adopted, whenever practicable. However, according to the applicant, it is not possible or feasible to use automatic/enclosed system in all cases due to technical or economic reasons. Therefore, some companies perform manual moulding. Although LEV is, according to the applicant, generally used in loading, melting and mixing phases of manual moulding, the ES includes also manual moulding without the use of LEV. In addition, although at most manual moulders melting and mixing are enclosed, some perform these steps manually in open containers, which may result in splashes and vapour exposure.

According to the literature, general good housekeeping practices, frequent cleaning, including immediate cleaning of any spillages and training of workers in the proper use of PPE (including fit testing of RPEs and frequent change and correct removal of contaminated gloves) is of utmost importance for the management of exposure and risks in both automatic and manual moulding. RAC notes that detailed information on the good housekeeping and training practices for the safe use of MOCA can be found from the literature, e.g. from the reports and guidance produced by UK Health and Safety Executive (HSE). However, although the applicant provided good examples from some individual companies applying these practises, it is not evident that these good practices related to housekeeping or training of workers are applied at all sites using MOCA. In addition, in the contributing scenarios these practises have been described only at the very general level.

Some companies perform surface sampling for MOCA in order to ensure the lack of contamination of surfaces, however this has not been done by all companies. Neither has biomonitoring of workers been performed by all companies. Since exposure to MOCA may vary widely also because of the individual working practices, biomonitoring is the only way to ensure the appropriateness and effectiveness of the implemented RMMs at workplaces. Availability of appropriate biomonitoring methods (urinary MOCA analysis) for all companies is, however, unclear, since according to RAC's knowledge, laboratories performing biomonitoring for MOCA might not be available in all countries. This creates difficulties for the assessment of the management of exposure to MOCA.

Risk characterisation

Exposure was assessed on the basis of biomonitoring data gathered by the applicant. This data were supported by the published literature data on exposure to MOCA, mainly from

UK. As described in Section 4, a rounded value of 10 µmol/mol creatinine is used for risk characterization for both ES1 and ES2, although the applicant's original assessment used a lower value for manual moulding. Excess cancer risk was calculated on the basis of the RAC reference dose response relationship for the carcinogenicity of MOCA (RAC/32/2015/10 rev 1) described for biomonitoring. Calculated cancer risks for workers are presented in Table 8. It needs to be remembered that these calculations include uncertainties, which arise from the very wide and all-inclusive description of the OCs and RMMs, and applicability of these values to maintenance and cleaning tasks.

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

WCS	Combined exposure (urinary MOCA)	Excess Risk
Combined ES1	10 µmol/mol crea	3.3×10^{-5}
Combined ES2	10 µmol/mol crea	3.3×10^{-5}

Indirect exposure

Exposure and risks of indirectly exposed workers were not assessed by the applicant. While inhalation exposure is likely to be low, there might be a possibility for contact with contaminated surfaces and dermal exposure of indirectly exposed workers. The number of possible indirectly exposed workers is also unknown. This creates an additional uncertainty for the assessment.

Exposure of end-users and consumers

In principle, the professionals (or consumers) using MOCA cured articles may be exposed to traces of MOCA in the products/surfaces of the products. The levels of unreacted MOCA in articles cured with MOCA are, however, low - generally well below 0.1%, but in some circumstances the levels may be close to 0.1%. Some companies (but not all) perform wipe and powdering tests to confirm low levels of unreacted MOCA in their products.

MvE exposure / local and regional

Although MOCA has low volatility, releases to the air may occur, for example, when MOCA is melted. LEV filters/scrubbers are not always in place to prevent air emissions and there is no data on the air emissions from these cases. Although process has no contact with water and direct releases to waste water do not occur, releases to the water may occur if washing of the empty containers are performed. Wastes coming from the process (including contaminated filters, clothing, and empty containers) are treated as hazardous waste.
Assessment of the exposure of MvE was made by modelling (EUSES 2.1).

Excess cancer risk was calculated on the basis of the RAC reference dose response relationship for the carcinogenicity of MOCA (RAC/32/2015/10 rev 1). Calculated cancer risks for MvE are presented in table 9.

Table 9: Excess risk estimates for 70 years exposure for MvE

	Exposure	Excess Risk
Local exposure	Inhalation	1.24×10^{-8}
	Oral	1.1×10^{-6}
Regional exposure	Inhalation	4.39×10^{-12}
	Oral	1.3×10^{-9}

Conclusion

RAC considers that RMMs and OCs described in the application are not appropriate and effective in limiting the risk to workers. The applicant did not define the minimum requirements for OCs and RMMs, which should be in place in order to achieve the described exposure and risk levels. RAC considers that the applicant has also included practices, which clearly do not represent the best practices in the field of occupational or environmental hygiene and for which the claimed exposures are not substantiated by the available measurement data. This applies especially to the exposure of workers, but partly also to the environmental releases and exposure of general population.

The current application covers both automated and manual moulding processes. According to RAC, automation and containment of the moulding process, including a glove box for the loading of MOCA, automatic transfer of MOCA to the reactor and enclosed system for melting and mixing phase can be considered to represent good practice and shall be adopted, whenever practicable.

Good general housekeeping practices (including frequent cleaning to prevent MOCA build-up around working areas), good individual working practices, and regular training in good industrial hygiene practices and in the proper use of personal protective equipment have a significant role in the management of exposure to MOCA. Although the applicant has provided good examples from some individual companies, it is not evident that these good practices are applied at all sites using MOCA. In addition, in the contributing scenarios these practises have been described only at the very general level.

Given these deficiencies in the application, strict conditions defining minimum standards for OCs and RMMs are in the view of RAC necessary to achieve the applicant's exposure and risk claims.

RAC is in the opinion that biomonitoring of workers and the measurement of surface contamination at the workplace are essential tools that have to be used for evaluation of the effectiveness and ensuring the appropriateness of the RMMs at workplaces. Although laboratories performing MOCA biomonitoring are available in EU, they might not be available in all countries. Small companies may need advice how to find laboratories providing these services in EU.

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

The applicant states that Suzhou Xiangyuan Special Fine Chemicals Ltd. (hereafter referred to as SXSC Ltd.) is the world's largest producer of MOCA. The production occurs entirely outside the EEA. MOCA is imported into the EEA in pellet form (516 tonnes per year, based on an average over 3 years). SXSC Ltd. is claimed to be also a major global producer of the alternatives to MOCA, which they also supply to the EEA market. The EEA MOCA supply chain of SXSC Ltd. is outlined in Figure 1 below (taken from the application for authorisation):

Figure 1: The MOCA supply chain (taken from the AfA):

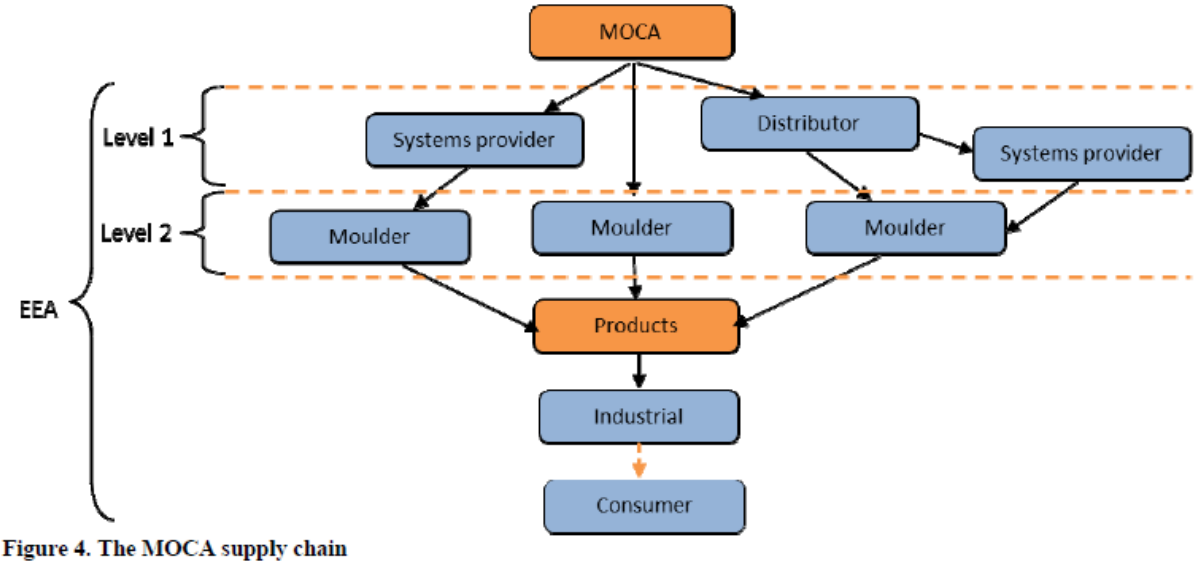


Figure 4. The MOCA supply chain

Level 1 of the supply chain covers 5 companies and level 2 covers about 89 moulders (estimated – for further details see section 8) spread across the EU. System providers sell cast polyurethane systems (e.g. prepolymers, curatives, additives, and also machinery) to moulders. There are also distributors, who only sell raw materials to moulders. Both, the system providers and distributors, have made available to their customers possible alternatives to MOCA and work with them extensively to find suitable alternatives for each of their products. All moulders in this supply chain are classed as micro-, small- and medium-sized enterprises.

Furthermore, the applicant points out that MOCA is used **across a variety of industry sectors** and in manufacturing of a **large number of products and product parts**. It is stated that most of the products made with MOCA are polyurethane elastomers for materials handling and machine parts. **Industries** using the respective products and parts include mining, minerals extraction and processing, paper and printing industry, packaging industry, fiber glass and glass manufacturing, door factories, factory machines for medical tests, medical implant manufacturing, steel and aluminium industries, oil and gas industry, textile and plastic industry, corrugated board industry, quarrying, windfarm industry and the wood and timber industry. Furthermore, the products are used in public transport, retail, motor vehicle manufacture, lifts and escalators, leisure industry, marine transport, dockside

and cargo handling, and parts are used also in aerospace, industrial vehicles, energy and the defence sector. The applicant highlights, that this is a non-exhaustive enumeration. **Products** made with a MOCA cured system include: wheels and rollers covered by polyurethane, technical machine parts, timing and other types of belts used in many applications (e.g. printers, money sorting machines, security cameras, sprinkler systems, etc.), textile and paper manufacturing and general machinery. MOCA cured systems are furthermore used for roller coating for any industrial sector, cone separators for the paper industry, roller covers for the steel industry, street furniture, sheets and scrapers. Polyurethane covered rollers are used especially in the steel, aluminium, paper, carton, wood and textile industry.

Products can be differentiated into large, medium and small sizes (defined by their weight in kg), which is, according to the applicant, an important differentiation when it comes to the analysis whether alternatives are feasible or not (for more details see further below).

The applicant briefly describes the process of producing cast polyurethanes, which are made from 3 main constituents: the **polyol**, the **diisocyanate** (which together form the prepolymer) and the **chain extender/curing agent** (e.g. MOCA). The prepolymer and MOCA react to produce molecules of very high molecular weight, having high performance elastomeric properties. MOCA is used almost exclusively with the TDI (Toluene diisocyanate) system, resulting in a product which has, according to the applicant, several advantages over other materials: the polyurethane is **relatively light**, it has **high abrasion/tear resistance**, **corrosion resistance** and it possesses **elastomeric or rubber-like properties** that allow the material to return to its original size and shape after it is stretched or compressed. The products can be **coloured** to suit certain needs/trends. Furthermore, the **machinery required** is comparatively **inexpensive**. Overall, the applicant claims that MOCA imparts to a cast polyurethane the following technical characteristics better than alternatives: **abrasion and cut resistance, humidity, resistance to hydrolysis, heat, cut and tear resistance, UV resistance, ozone resistance, resistance to radiation, and good fire retardant properties**. These features were specifically identified in the supply chain. In addition to delivering better technical properties, MOCA compares favourably in relation to **cost considerations**, **processability** of the reagent, **robustness** and the **long history** of **formulation** and **processing knowledge**.

According to the applicant it is not sufficient to only compare technical parameters of MOCA with possible alternatives, but it is necessary to also consider the overall performance of the product to be manufactured as the technical performance of the end product will change when using a different polyurethane system. According to the applicant, necessary requirements of alternatives are the following:

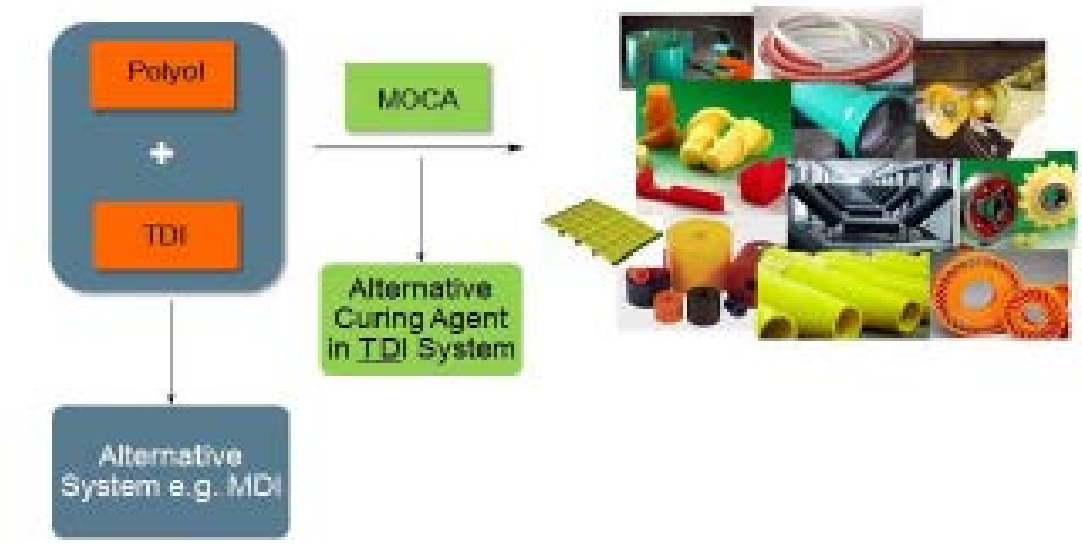
- any alternative must result in products that meet the technical requirements and expectations of the customers,
- the processing must be easy in order to not give batch-to-batch variations that may cause service life problems and cost issues with rejected parts,
- it must be chemically stable,
- it must be cost effective in order for the moulder to be able to maintain his business in the face of competition from outside the EEA.

For identifying alternatives, the applicant performed patent and scientific literature searches. Furthermore, system providers and moulders have been interviewed via questionnaires and teleconferences. The applicant states that none of them is currently in

the position to engage in *novel* R&D activities, i.e. they do not have the facilities or the expertise to design, synthesise and industrialise new chemicals/molecules themselves but must rely on those reagents that are currently commercially available. However, they test those commercially available possibilities that have been industrialised by chemical manufacturers already. The patent and literature search as well as the interviews with system providers and moulders revealed two possible options for substituting MOCA:

- **A like-for-like substitution of MOCA within a TDI System**:
  the most commonly cited substances by moulders in the questionnaire were Dimethylthiotoluenediamine (DMTDA, 80 % also known as Ethacure), Bis(4-amino-2-chloro-3,5- diethylphenyl)methane (MCDEA, 48 %), and 3,5-Diamino-4-chlorobenzoacid isobutylester 1604 (26 %); these were therefore identified by the applicant as the preferred alternative curing agents for TDI based systems
- **The use of another system, e.g. an MDI-based system, not using MOCA:**
  85% of the respondents to the questionnaire stated that they had tested or are currently using an MDI system

Figure 2: Possible approaches to replace MOCA (taken from the AfA):



Research includes the development of a new recipe, specific for each product, parts processing tests and technical tests, financial evaluation as well as manufacturing. These activities are currently carried out by moulders together with their system providers.

On request of SEAC, the applicant provided a matrix, which should give an overview over types of products (small – medium – large), different properties and their requirement rating, the assessed alternatives (like-for-like alternatives or alternative systems) and whether or not those are regarded being technically or economically viable (indicated in green), potentially viable (indicated in orange) or not viable (indicated in red):

Figure 3: Technical and cost comparison of MOCA to the identified alternatives (as provided by the applicant):

Requirement Rating	Small parts	MOCA	MCDEA	Ethacure	1604	MDI/BDO	MDI
High	Mechanical Properties						
Medium	Pot life/Cure Time						
Medium	Processing						
Low	Environmental Properties						
High	Availability						
High	Pass rate compared to MOCA	>95					
	Cost ratio of the system compared to MOCA	1	8	3	5-7	0.9	1.2-1.3
Requirement Rating	**Medium parts**	**MOCA**	**MCDEA**	**Ethacure**	**1604**	**MDI/BDO**	**MDI**
High	Mechanical Properties						
High	Pot life/Cure Time						
High	Processing						
Medium	Environmental Properties						
High	Availability						
High	Pass rate compared to MOCA	>95					
	Cost ratio of the system compared to MOCA	1	8	3	5-7	0.9	1.2-1.3
Requirement Rating	**Large parts + Special cases**	**MOCA**	**MCDEA**	**Ethacure**	**1604**	**MDI/BDO**	**MDI**
High	Mechanical Properties						
High	Pot life/Cure Time						
High	Processing						
Medium	Environmental Properties						
High	Availability						
High	Pass rate compared to MOCA	>95					
	Cost ratio of the system compared to MOCA	1	8	3	5-7	0.9	1.2-1.3

Key:		
Viable	Potentially Viable	Not viable

The matrix developed by the applicant indicates that there are differences in the (technical) viability of alternatives depending on the size of the article (product/product part).

Technical feasibility

The following alternatives (substances and technologies/systems) were assessed by the applicant as those have been most commonly cited by system providers and moulders during the interviews:

- **DMTDA (Dimethylthiotoluenediamine, Ethacure® 300):** DMTDA is a liquid aromatic diamine with low toxicity. It is claimed to be an effective curative for polyurethane cast elastomers and to be in use since decades as an alternative to MOCA. DMTDA has higher tensile properties compared to MOCA and it is liquid at room temperature, which facilitates processing as it does not need to be melted. However, the applicant states that most mechanical properties of the products produced with DMTDA are not as good as products that were produced with MOCA, e.g. DMTDA leads to lower tear strength, lower compression set and hydrolysis resistance, etc. Furthermore, parts made with MOCA have no odour, whereas parts made with DMTDA are claimed to have an extremely unpleasant odour. A third party commented that they import DMTDA and have developed the product further and are now able to produce a low odour quality of Ethacure 300®. They also state that Ethacure® 300 offers a wide processing latitude and control over reactivity and produces tough parts with desired heat aging and mechanical properties, which closely match or are even better than MOCA. However, according to the applicant, the pot-life of DMTDA is shorter, which leads to processing implications, specifically for larger products. It could result in cracking and a weakening of the entire product. These technical deficiencies are also mentioned in supportive comments received during the public consultation on the application. Overall, although moulders stated that they would possibly switch to DMTDA in case MOCA is no longer available to them, as this is regarded being the quickest and easiest direct substitution, it won't offer the same dynamic performance to their customers. A full switch to DMTDA is expected to lead to problems with reduced product life and performance.

- **3,5-diamino-4-chlorobenzoacid isobutylester (Addolink® 1604):** 1604 is an crosslinking aromatic diamine for heat curing polyurethane prepolymers and is, according to the applicant, in use as an alternative to MOCA since 30 – 40 years. Some of the supply chain members consulted by the applicant replied that 1604 would be the best direct replacement for MOCA for some applications. 1604 is claimed to enable longer reaction times to be achieved so that large volume products can be manufactured. A third party commented that their customers are already in the process to evaluate Addolink® 1604 as an alternative to existing systems and confirmed that its longer pot life is a big advantage for casting large parts. Manual processing is also possible. However, 1604 must be melted before processing at the recommended processing temperature of ~100°C. Temperatures above 120°C give inferior elastomers and at temperatures above 170°C, 1604 begins to decompose, generating gaseous products which can cause high pressure in closed systems. Furthermore, the applicant states that moulders reported cracking of products leading to increased losses from rejected pieces. Furthermore, the production of 1604 is claimed to cause higher pollution and waste water compared to MOCA; however, this claim was not substantiated further.

- **MCDEA (Bis(4-amino-2-chloro-3,5-diethylphenyl)methane:** The applicant reports that MCDEA is an aromatic amine and is already in use as an alternative curing agent/chain extender to MOCA since many years. Products produced using MCDEA show desirable properties, such as good toughness, abrasion resistance, resilience and better temperature range properties. The substance is said to be used in niche applications, where such properties are required and a premium price can be paid. However, such products have, according to the applicant, the tendency to crack when undergoing polymerisation. Feedback from the supply chain suggests that it may be suitable for some very small and specialised products, but not for medium or larger products. Furthermore, moulders reported that MCDEA is not practical for the production of most cast polyurethane products because of its short pot-life.

- **MDI based systems (MDI/BDO system, LFMDI/HQEE system):** The applicant states that besides TDI, MDI is the other most widely used diisocyanate in the cast polyurethane industry. The most common curing agents used within a MDI system are **BDO** (Butan-1,4-diol) and **HQEE** (Hydroquinone bis(beta-hydroxyethyl)ether). The applicant reports that diamines (like MOCA) are generally preferred for some applications, as they have shorter curing times and give overall better properties, e.g. higher tensile strength and higher hardness than MDI-bases systems. MDI-based systems are claimed to also require a much more accurate mixing ratio between the chain extender and the pre-polymer than the TDI/MOCA system in order to achieve the desired properties. The MDI process is regarded as being less robust than the TDI/MOCA process. 85% of moulders that were surveyed reported that they had tested or are currently using MDI systems, but they do not regard it as a viable alternative for all products they produce. Where substitution is possible, an alternative was already implemented. Shrinkage of the polyurethane within the mould/coating, which seriously impacts some final products, seems to be a problem when using MDI-based systems. Furthermore, MDI-systems are more strongly exothermic and release heat more rapidly than TDI-systems. This may cause problems in large products, i.e. cracking. For the **MDI/BDO system**, additional processing issues are reported such as voids or bubble formation within the product. Material suppliers and system providers of MDI/BDO-systems advised moulders that they should, in theory, be able to reach equivalent technical characteristics for their products to those produced with the TDI/MOCA-system. However, tests showed that in practice, a polyurethane cured with a MDI-system is not able to replicate the performance of TDI/MOCA. Therefore, these systems are not regarded as a technically feasible alternative by the applicant. The **LFMDI/HQEE-system** is considered to have better temperature resistance, tensile strength, abrasion resistance and elasticity compared to TDI/MOCA. A third party commented that the LFMDI/HQEE system is technically feasible and considers it as a viable alternative to the MOCA/TDI system. However, according to the applicant, this system is said to have demanding temperature requirements, possibly leading to poor miscibility with the consequence that the reaction might not occur as expected. Furthermore, the applicant states that this system is said to require a high performance, high temperature, multi-tank pouring machine which leads to economic feasibility concerns. As with the MDI/BDO-system, the LFMDI/HQEE-system easily absorbs water/moisture from the atmosphere which causes degradative products on reaction, leading to e.g. bubbles in the final product. Moulders consulted reported that tests

on the final product, under real working conditions, have shown to give non-viable products. Furthermore, moulders stated that any production that could be moved to a MDI-system has already happened and therefore there is not much additional capacity to move to this system.

For the above mentioned alternatives for MOCA in TDI-based systems as well as for the MDI-based alternative systems, the summary of the applicant's findings as regards technical feasibility is attached to this opinion in Annex 2.

Furthermore, a comparison of different required properties of alternatives (substance and technology/system) compared to the TDI/MOCA system is given in figure 3 in section 7.1 above.

In summary, in the applicant's view, overall, none of the assessed alternatives (substances and/or technologies/systems) are feasible from a technical point of view, in particular as far as larger and specialized products and product parts are concerned. The fact, that some of the assessed alternatives are in use already for decades, but were not able to fully replace MOCA, is, according to the applicant, a further confirmation that MOCA is not universally substitutable to date. The applicant concludes that a significant percentage (the exact figure is claimed confidential by the applicant) of the value of the products currently moulded with MOCA has no technical solution for substitution.

Economic feasibility

For the assessed alternatives, the applicant provides the following information. Third parties' comments are considered as well:

- **DMTDA (Dimethylthiotoluenediamine, Ethacure® 300):** the substance is approximately 3 times more expensive than MOCA. One third party confirmed that Ethacure® 300 has overall higher raw materials costs than MOCA but these extra costs can be offset by lower energy costs and reduced requirements for managing worker exposure and health surveillance in accordance with carcinogens directive. However, this information was not substantiated by any supporting evidence but SEAC notes that DMTDA is not classified as carcinogenic so no health surveillance in accordance with the carcinogens directive is required for DMTDA.
- **3,5-diamino-4-chlorobenzoacid isobutylester (Addolink® 1604):** the price is 5 – 7 times that of MOCA, which is claimed to be the reason why this alternative is only used in an estimated 1% of the world-wide market. One third party confirmed the higher cost of Addolink® 1604 which is due to the multi-step of its synthesis.
- **MCDEA (Bis(4-amino-2-chloro-3,5-diethylphenyl)methane):** the substance is approximately 8 times more expensive than MOCA. In addition a higher quantity (~30%) is needed when using it as replacement of MOCA, producing the same output.
- **MDI based systems (MDI/BDO system, LFMDI/HQEE system):** the MDI/BDO system is a 10% cheaper system than the TDI/MOCA system. In contrary, the LFMDI/HQEE system is estimated to be 20 – 30% more expensive than the TDI/MOCA system.

For the above mentioned alternatives for MOCA in TDI-based systems as well as for the MDI-based alternative systems, the summary of the applicant's findings as regards economic feasibility is attached to this opinion in Annex 2. Furthermore, the cost ratios of

each alternative (substance and technology/system) compared to the TDI/MOCA system is given in figure 3 in section 7.1 above. During the opinion making process of RAC and SEAC, the applicant provided further information on economic feasibility, which was claimed confidential. Overall, one (though non-supportive) third party stated that the costs of the final products are about 15% higher if alternatives are used instead of MOCA.

Another aspect about economic feasibility is linked to technical deficiencies of some alternatives (as pointed out above) as far as rejected parts are concerned. Indeed, some of the products and products parts cured with MOCA are used in sectors with high safety and qualification standards (e.g. oil and gas industry or defence sectors) for which any technical failure could result in huge environmental damage and potential injury as well as very high costs of replacement of defective parts. Further respective information provided by the applicant was claimed confidential.

In summary, for most of the alternatives (substances and/or technologies/systems) the applicant expects an increase in price in case of substitution. Moulders have reported that their customers would not accept a substantial price increase of the final products, i.e. they cannot pass-on any higher costs further down the supply chain. In addition, many of the moulders export their products outside of the EEA, and therefore have to be price competitive to moulders producing outside the EEA. Furthermore, the applicant states that moulders, which are mainly micro-, small- or medium-sized enterprises, would not be able to absorb the increased reagent costs into their profit margin. As a consequence of the price increase, moulders will likely lose customers to the non-EEA cast polyurethane producers, who are able to continue using MOCA. Overall, the applicant concludes that none of the assessed alternatives are feasible from an economic point of view.

Conclusion

SEAC notes that the scope of this application for authorisation is broad. It covers a very large number of different products and product parts produced for a wide range of different industries (as pointed out above). The applicant states that even the smallest moulders have large product portfolios, covering several hundred different products: 30% of moulders produce 10-100 different products per year; 25% produce 100-1,000 different products; 40% produce more than 1,000 different products. On average, the moulders have 1,500 products and more than 400 customers per year. Furthermore, SEAC understood (confirmed by the applicant and third parties) that these products are often very specific (engineering) solutions to a specific “problem” as products differ in size and (technical) requirements, therefore, a general, overall analysis of alternatives based on technical parameters of MOCA and its potential alternatives can hardly be performed, but rather a product specific evaluation would be necessary. Although it is not unique only for this application for authorisation, SEAC agrees that it makes the analysis of alternatives very complex, specifically in (upstream) cases where the use applied for comprises a broad scope.

As far as the applicant’s **search for alternatives** (substances and/or technologies) is concerned, SEAC perceives this as being complete. During the public consultation several third parties claimed alternatives being feasible and available for the use applied for. However, these alternatives were already addressed by the applicant in its assessment, i.e. no new alternatives were brought up during the opinion development process of RAC and SEAC.

As far as the applicant’s **assessment of alternatives** (substances and/or technologies/systems) is concerned, SEAC considers this assessment to be brief, generic and mostly qualitative due to the above mentioned reasons. Rather than performing an

alternatives' assessment based on the requirements of specific products/product parts covered by his application, the applicant concluded that overall, no technically and economically feasible alternatives exist. This conclusion of the applicant is, in SEAC's view, based on some, rather *specific*, applications with *specific* requirements (safety standards, qualification and certification standards), where substitution is indeed not regarded being feasible at the sunset date (based on confidential information available to SEAC, which cannot be disclosed in this opinion). This approach, in addition to the broad scope, gives rise to uncertainty regarding whether or not alternatives are already available and feasible for the/some applications covered, or will become so in the short term and for which products within which industries this would be the case. As stated above, the applicant provided additional information on request of SEAC, specifically on technical aspects of substitution. Further information was also submitted as regards economic feasibility. Furthermore, an overview of industry sectors and the respective impacted product parts, that would: i) change the curing agent within the TDI system, ii) change the system (e.g. to (LF)MDI), iii) not be able to replace MOCA at all, was given. This confidential information is regarded as being useful by SEAC as it further clarifies and supports the necessity to use MOCA as a curing agent/chain extender in cast polyurethane elastomer production within *certain* industries for *some* specific products/products parts even after the sunset date. However, the additionally provided information could not eliminate the above-mentioned uncertainties surrounding the applicant's analysis of alternatives.

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

☐ YES

☒ NO

Justification:

As stated by the applicant, the reason for filing this application for authorisation is to support the micro, small and medium sized members of its supply chain who are claimed to be currently not in a position to substitute MOCA for technical and economic reasons.

Applicant's conclusion on technical feasibility of the alternatives assessed

The applicant concludes that currently none of the alternatives (substances and/or technologies/systems) that have been assessed within his application for authorisation provides an overall technical solution to substitute MOCA for the overall use applied for and for every single product and product part covered. The applicant confirmed that substitution of MOCA has already commenced in the EU for those products, where substitution is possible and feasible and that 80% of the EU cast polyurethane production has already phased out MOCA-based technologies. However, as stated above, for a significant percentage of the value of the products currently moulded with MOCA there is no technical solution for substitution: there are several industries producing products/product parts that still require MOCA as a curing agent/chain extender due to multiple parameters which include technical, cost, processing and dynamic performance parameters. The applicant emphasises that when deciding on technical feasibility, a simple comparison of technical parameters is insufficient and will never give a true insight into the technical feasibility of substitution. Substitution is dependent on the product size (as pointed out above) and product-specific requirements (high dynamic performance, long product lifetime, etc.) and a suitable engineering solution

– therefore must be judged by multiple parameters. Even non-supportive third parties confirm that there are no “drop-in” replacement alternatives that meet the cost-benefit-profile of MOCA. Choosing the right alternative solution is a matter of the needs of the application and the ability of the various alternatives to best meet these needs. In summary, the applicant concludes that substitution is technically not feasible for the use applied for at the sunset date.

Applicant’s conclusion on economic feasibility of the alternatives assessed

The applicant concludes that none of the assessed alternatives (substances and/or technologies/systems) are feasible from an economic point of view. Prices of raw materials are generally higher; customers won’t accept higher prices and this would lead to a loss of business for moulders, as they are not able to pass on higher costs to customers, who could purchase their products cured with MOCA outside the EEA; some of the assessed alternative technologies would possibly require modifications or even the purchase of specific machinery. One moulder reported that the replacement of their moulds could cost millions of Euros for their specific product types given the thousands of moulds they use at present. However, no further substantiation of this claim was provided to SEAC.

The summary of the applicant’s conclusion on technical and economic feasibility is given in Table 10 below.

Table 10: Applicant's conclusion on technical and economic feasibility of assessed alternatives (taken from the AfA):

Conclusion on like-for-like alternatives	**DMTDA:** DMTDA is not a feasible alternative to MOCA due to technical reasons for larger parts; and technical and economic reasons for small/medium sized parts.	**1604**: Cracks in some parts mean that this is not a technically feasible alternative for some products. 1604 is not a viable alternative to MOCA due to economic feasibility. The ciment reagent cost is too high for SME's to absorb. The availability of it in the required Quantity and quality is also a matter of concern.	**MCDEA**: Given the short pot-life it is not considered a technically feasible alternative. Additionally. MCDEA is not a viable alternative to MOCA due to its cost. The ciment reagent cost is too high for SME's to absorb. The availability of this alternative in the
Conclusion on alternative systems	**MDI/BDO**: As mentioned already, most moulders have MDI production capabilities, but are unable to substitute all applications. Though the MDI/BDO system is cheaper than TDI/MOCA it fails to provide equivalent technical properties for some applications. Additionally, the processing is more difficult and the pot life is shorter meaning that this is not a technically feasible alternative.	**MDI/others**: Most moulders have MDI production capabilities, but are unable to substitute all applications as it fails to provide equivalent technical properties for some applications. Additionally, the processing can be more difficult and the pot life can be shorter meaning that this is not a technically feasible alternative.	

Conclusion

SEAC concludes that the scope of this application for authorisation is broad, which gives rise to uncertainty when assessing and concluding on the (technical and economic) feasibility of alternatives. This is not unique for this specific application for authorisation, but rather common with other broad-scope upstream applications. However, in SEAC's view, the uncertainties within this application regarding substitution are specifically high due to some characteristics that are specific to this case:

- as raised by third parties, and as confirmed by the applicant, 80% of the EU cast polyurethane production has already phased-out MOCA-based technologies, and some producers have switched to MOCA-free solutions more than 20 years ago already;
- substitution is ongoing already and there are products on the market where alternatives (substances and/or technologies/systems) are already in use and therefore technically and most probably economically feasible; this statement was confirmed by the applicant; third parties that submitted detailed comments during

the public consultation were confident, that substitution is possible and feasible for *all* applications covered by this authorisation already by the sunset date; the applicant did not agree with this statement emphasizing that, given the large variety of products/product parts covered and their specific requirements as well as the huge amount of industry sectors using products produced with MOCA, no universal alternative exists;

- SEAC has no concrete information about the proportion and the specific products/product parts and industries that are able/not able to substitute by the sunset date. SEAC asked the applicant for a more specific categorisation or breakdown of products (based on any possible distinguishing feature such as functionalities or technicalities) and/or an exhaustive list of products and products parts and/or industries where substitution is feasible already in order to clearly identify those but drawing an exhaustive list is claimed by the applicant to be not possible, given the large portfolio of products currently manufactured by moulders and covered by this upstream application; This lack of specific information limits the ability of SEAC to draw a clear picture of the actual possibilities of substituting within the scope.
- the applicant claims, however, that there is currently no technical solution for substitution for a significant percentage of the value of the products currently moulded with MOCA; however, this also and implies again that there is indeed a technical solution for a certain percentage.
- in SEAC's view, the above issues overall would have required a product/product parts specific assessment for this application for authorisation, based on respective requirements of affected products/product parts (e.g. safety standards, qualification schemes, etc.) whereas the applicant performed the assessment of (technical and economic) feasibility on a rather general basis, covering all uses of MOCA as a curing agent/chain extender. SEAC thus regrets the low quality of the alternatives assessment given the complexity of the scope covered by this application.

In conclusion, SEAC received contradicting information from the applicant and third parties in this respect. Based on this information, it remains unclear whether overall substitution is yet feasible (as claimed by third parties). In case it is not (as claimed by the applicant), it is also unclear for which proportion of products/product parts and for which products/product parts it is not feasible by the sunset date. Therefore, there is a contradiction in the "completeness" of substitution which couldn't be totally clarified during SEAC's opinion making process.

Based on confidential information provided by the applicant during the opinion making process, SEAC got further insight into the substitution efforts undertaken by downstream users and the reasons for failure. **SEAC can agree with the applicant's conclusion that currently, MOCA is still needed as a curing agent/chain extender in the cast polyurethane elastomer production for certain products/product parts within certain industry sectors as substitution is not technically and/or economically feasible by the sunset date.** In this regard, the applicant informed SEAC that for small-sized articles (weight below 10 kg), substitution might be feasible earlier than for medium-sized articles (weight between 10 and 100 kg) and for both of them substitution is regarded as being feasible earlier than for large sized articles (weight over 100 kg) and articles requiring certain specific technicalities, such as high dynamic performance, long product lifetimes and/or good heat aging properties. However, this information does not resolve the

uncertainties due to the broad scope of this authorisation application in a way that it would ensure that substitutions takes place where already (technically and economically) feasible.

As regards economic feasibility, SEAC cannot conclude on the economic feasibility of alternatives due to the fact that economic feasibility is discussed in the application for authorisation very briefly and mainly qualitatively. Furthermore, a substantiation of the respective claims is missing. During the opinion making process, further confidential information on economic feasibility was submitted. For assessing the economic feasibility of alternatives, costs of developing and transitioning to achieve technical feasibility can be considered. These costs were, however, not considered by the applicant. The applicant concludes that the overall costs for alternatives are expected/reported by industry to be higher, but due to the lack of a detailed assessment, SEAC cannot conclude on the economic feasibility of alternatives.

In summary, SEAC agrees that there are products/product parts and industries within the scope of this authorisation application, where substitution is not (technically and economically) feasible by the sunset date, mainly based on confidential information available to SEAC. However, due to the broad scope of the application and shortcomings in the assessment such as presented above, as well as contradicting information provided by third parties, SEAC finds it likely that there are indeed applications covered, where substitution is already feasible or will become so in the short term. In fact, it is not clear to SEAC when alternatives will potentially become available for specific products/product parts for specific industries covered by this application for authorisation. The uncertainties pointed out above are taken into account by SEAC in the recommendation for the review period and the conditions for the review report.

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

Description:

The applicant describes following substitutes for MOCA:

- Dimethylthiotoluenediamine (Trade Name: Ethacure® 300). The main hazard of this substance for humans is skin sensitization. It is also classified for aquatic toxicity, but is has no recognized carcinogenic, mutagenic or reprotoxic (CMR) properties, persistent, bioaccumulative and toxic (PBT) or endocrine disrupting (ED) properties.
- 3,5-diamino-4-chlorobenzoacid isobutylester (1604) is an irritant substance, which does not have any recognized CMR, PBT or ED properties.
- Bis(4-amino-2-chloro-3,5-diethylphenyl)methane (MCDEA) is classified only for aquatic toxicity and it has no CMR, PBT or ED properties.
- One alternative is to change MOCA/TDI based systems to MDI based systems. These systems use butan-1,4-diol, (BDO) and hydroquinone bis(beta-hydroxyethyl)ether (HQEE) as curing agents. These substances has no recognized CMR, PBT or ED properties.

The applicant has not performed a detailed risk assessment of the alternatives, but provided only hazard information. The available hazard profile of the alternatives does not, however,

raise any significant health or environmental concerns. Potent respiratory sensitizers, diisocyanates, are used both in MOCA and in non-MOCA based systems.

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:

On the basis of the hazard information provided by the applicant and third parties during the review process, the available alternatives do not raise concerns for CMR, EDC or PBT properties. Ethacure® requires skin protection due to its skin sensitizing properties but in all cases these alternatives are likely to result in the reduction of risk.

Conclusion

There are substitutes available, which are likely to result in the reduction of risk.

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:

No technically or economically feasible alternatives will be available at the sunset date.

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 (workers and the general population via the environment) provided by the applicant. For workers risk assessment, RAC used the literature supported value of 10 µmol/mol creatinine for workers risk characterization for both, manual and automatic moulding. Figure 5 reflects the expected statistical number of cancer cases for an exposure over the working life of workers (40 years) and entire life for general population (70 years). In addition, the expected statistical number of cancer cases for an exposure over the review period requested (12 years) and for one year of exposure are presented.

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

Furthermore, the applicant calculated non-fatal cancer cases using the survival rate based on a mortality rate for lung cancer of 80% for both sexes, based on international cancer statistics, International Agency for Research of Cancer (www.iarc.fr), as also cited in ECHA's guidance "Valuing Selected Health Impacts of Chemicals: Summary of the Results and a Critical Review of the ECHA Study" (December 2015, ECHA). However, these figures were incorrectly calculated by the applicant, as RAC's dose response relationship for MOCA was incorrectly interpreted. RAC's dose response relationship for MOCA is based on cancer findings in animals, which include both fatal and non-fatal cancer. Therefore, the below figures on excess lung cancer risk represent the sum of fatal and non-fatal cancer, and not fatal cancer only, as assumed originally by the applicant. The calculations were therefore updated by SEAC. However, SEAC notes that the difference in the end-result is minor. Moreover, the applicant's incorrect approach did yield even more conservative figures. The updated calculation by SEAC gives 1.24 fatal and 0.31 non-fatal cancer cases for 40/70 years of exposure and 0.22 fatal and 0.05 non-fatal cancer cases for the review period requested (12 years).

Table 11: Estimated additional statistical cancer cases (40/70 years of exposure, RP applied for, 1 year of exposure):

	Excess lung cancer risk	**Number of exposed people**	**Estimated statistical cancer cases**		
			40y	**12y**	**1y**
Workers					
Directly exposed workers – combined exposure	3.4×10^{-5}	213	7.2×10^{-3}	2.2×10^{-3}	1.8×10^{-4}
Indirectly exposed workers	Not assessed				
TOTAL workers – fatal cancer			5.79×10^{-3}	1.74×10^{-3}	1.45×10^{-4}
TOTAL workers – non-fatal cancer			1.45×10^{-3}	$4{,}35 \times 10^{-4}$	$2{,}90 \times 10^{-5}$
TOTAL – Workers – fatal+non-fatal			**7.2×10^{-3}**	**2.2×10^{-3}**	**1.8×10^{-4}**
General population exposed via environment, 70y exposure					
Local	1.1×10^{-6}	1,033,557	1	0.17	0.014
Regional	1.3×10^{-9}	304,997,810	0.4	0.07	0.006
TOTAL – General population - fatal cancer			**1.12**	**0.19**	**0.02**
TOTAL – General population- non-fatal cancer			**0.28**	**0.05**	**0.004**
TOTAL – General population fatal+non-fatal			**1.4**	**0.24**	**0.02**
TOTAL both, workers and general population			**1.41**	**0.24**	**0.02**

It has to be noted that RAC identified an uncertainty related to consumer exposure from the final product and this uncertainty is addressed in RAC's condition (requirement for all MOCA users to ensure by measurements that levels are <0.1% - see section 9). However, as RAC did not consider it necessary to assess exposure and risks to consumers, SEAC did not further investigate this issue.

Costs of continued use (HH)

For calculating the costs of continued use of MOCA, **excess lung cancer risks for workers** and the **general population exposed via the environment, local and regional,** were assessed. The applicant used the reference dose-response relationship (DRR) confirmed by RAC for the carcinogenicity of MOCA. In the first instance, the applicant incorrectly

addressed lung cancer and intestinal cancer, but MOCA has not shown to cause intestinal cancer and therefore no respective dose-response relationship was published. Therefore, on request of RAC and SEAC, the applicant updated its calculations accordingly. As can be seen from figure 5 above, most of the cancer cases (approximately 99%) are related to the exposure of the population via the environment.

Health impacts for workers:

The supply chain of MOCA (see figure 1 in section 7.1) consists of two levels, level 1 covering the importers (being distributers and system providers) of MOCA, which are known to be 5 companies in the EEA. From survey responses/interviews with these 5 companies, the total number of MOCA moulders, level 2 of the supply chain, was estimated being a total of 89 companies with a potential of **213 workers to be exposed to MOCA**. This number of workers exposed is estimated from survey responses according to which there is a potential exposure of 0.41 workers per tonne of MOCA imported (516.26 t/a). This gives a number of 213 workers at all levels in the supply chain in the EU that have the potential to be exposed to MOCA during the normal course of their work The manual and automated processes are described in separate exposure scenarios. However, as pointed out above, RAC used the literature supported value of 10 µmol/mol creatinine for workers risk characterization for both, manual and automatic moulding. Therefore, for both exposure scenarios (for manual and automated moulding) an excess lifetime risk (ELR) of 3.4×10^{-5} is assumed by RAC (see section 6 above). This ELR refers to a working lifetime risk with continued working-daily exposure. In order to use the ELR for this application for authorisation and in order to compare the monetised human health impacts to the benefits of continued use of MOCA, its value was adapted by the applicant to the review period applied for, which is 12 years. Furthermore, the mortality rate for lung cancer was estimated by the applicant to be 80%, incorrect calculations of fatal and non-fatal statistical lung cancer cases due to a misinterpretation of RAC's dose-response relationship were corrected by SEAC (as pointed out above).

Health impacts for the general population exposed via the environment, local and regional:

Based on the survey performed by the applicant, moulders are present in Belgium, Denmark, France, Italy, Ireland, Greece, Hungary, Portugal, Spain, the Netherlands and the United Kingdom. The applicant therefore regards exposure to the general population being most relevant for inhabitants in these countries. The applicant gives an overview of the population density used for their respective calculations, given in Table 12 below.

Table 12: Population density used for calculation of potential exposure (taken from the AfA):

Country	Population	Surface area (km²)	Population density/km2
Belgium	11,204.000	30.326	369.5
Denmark	5.627.240	42.959	131.0
France	63.920.200	543.965	117.5
Italy	60,782.700	295.113	206.0
Ireland	4,605.500	68.394	67.3
Greece	10,903.700	130.82	83.3
Hungary	9.877.370	93.028	106.2
Portugal	10,427,300	92,212	113.1
Spain	46,512,200	501,757	92.7
The Netherlands	16,829,300	33,718	499.1
The United Kingdom	64,308,300	242,509	265.2
Total	**304,997,810**	**2,074,801**	**147.0**

For calculating the number of exposed people living around the 89 moulding factories (for man via the environment, local), an area of a radius of 5 km is chosen (79 km²) which adds up to **1,033,557 people exposed locally** (89 × 79 × 147). For calculating the number of exposed people for man via the environment, regional, the total population of the 11 above listed countries is chosen which adds up to **304,997,810 people exposed regionally**.

Monetisation of human health impacts:

In order to evaluate the additional cancer cases in monetary terms, the applicant used the approach suggested in the ECHA report "Valuing Selected Health Impacts of Chemicals: Summary of the Results and a Critical Review of the ECHA Study" (December 2015, ECHA):

- ➔ the latency period for developing lung cancer among workers is assumed to be 10 years (see e.g. Brown et al. 2012)
- ➔ Discounting rates of 2% and 4%
- ➔ Use of lower (€ 3.5 million) and upper (€ 5 million) values of the statistical life (VSL), as well as value of morbidity due to cancer (€ 0.41 million)

With the above approach and assumptions, the value of a cancer case with 10 years latency would be between **€ 2.2 million at the lower range** and **€ 3.6 million at the upper range**.

The applicant applied these figures to the quantified human health impacts (workers and man via the environment, local and regional) and ends up with the below listed amounts, considering a 12 years review period:

Table 13: Monetised human health impacts, applicant's approach adjusted by the applicant and RAC/SEAC

Estimated statistical cancer cases (12 yrs):		Monetised human health impacts	
		Lower bound (2,200,000€)	Upper bound (3,600,000€)
Workers	2.2×10^{-3}	€4,840	€7,920
General population - local	0.17	€377,143	€617,143
General population - regional	0.07	€150,857	€246,857
TOTAL	**0.24**	**€532,840**	**€871,920**

SEAC stresses that these figures are not available in the original application for authorisation, due to the above mentioned necessary adjustments that were made by the applicant and RAC and SEAC during the opinion making process (i.e. correction of wrongly calculated intestinal cancer cases, wrongly applied dose-response relationship of MOCA (fatal / non-fatal cancer cases) and the alignment of the two exposure scenarios (for manual and automated processes).

The applicant did not provide a sensitivity analysis on the monetised human health impacts.

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

For calculating the benefits of continued use of MOCA the applicant set up the non-use scenario and described and assessed (qualitatively, where possible quantitatively (incl. monetisation)) direct economic impacts (impacts on moulders), wider economic impacts (indirect impacts on supporting industries) and social impacts (job losses) for different actors in the supply chain. According to the applicant, these assessments have been done conservatively. However, in addition, a sensitivity analysis (Monte Carlo simulation for economic and wider economic impacts) was performed.

The non-use scenario:

The non-use scenario depends, according to the applicant, on the role of the actor in the supply chain:

- The NUS for Suzhou: Suzhou Xiangyuan Special Fine Chemicals Ltd. states that the reason for filing this authorisation application is to support the micro-, small- and medium-sized members of Suzhou's supply chain, who are claimed to be currently not in a position to substitute MOCA due to the above mentioned technical and economic reasons. To Suzhou itself, not granting the authorisation would only lead to a minor impact, as it informed SEAC that it is able to adjust sales of MOCA to outside of the EEA where MOCA use is still allowed, and from where European customers can source some (small and medium sized) parts. Furthermore, those moulders that can substitute MOCA with a less suitable alternative are likely to be

supplied from Suzhou's inventory of more expensive alternative curing agents/chain extenders as well.

- The NUS for system providers and distributors (level 1 companies, a total of 5): system providers and distributors have an array of reagents that they can supply to the EEA market. They do not solely rely on MOCA-sales. Even though an initial loss of business is expected in case of the non-use scenario, they are expected to be able to offset this loss by providing their technical knowledge of alternative technologies to moulders, as they remain the main source of all cast PU related reagents and equipment for moulders in the EEA. The impact on this level of the supply chain is therefore regarded by the applicant to be negligible.

- The NUS for moulders: the applicant estimated that there are 89 moulders in level 2 of the supply chain, distributed across the EU. The applicant states that the information about the number of moulders in the supply chain were given by system providers that supply MOCA to those companies. According to the survey carried out by the applicant, it is known that there is a defined number of moulding companies that does not exceed 120 businesses. The reason for assuming a total of 89 companies was explained by the applicant to SEAC, but the respective information is claimed confidential.
  The applicant states that level 2 of the supply chain consists of three different types of moulders, depending on their type of business: **generalists (60%)**, **specialists (15%)**, and **mixed moulders (25%)**:
  1. **Generalists**, producing make-to-order products, low quantity per product, serving a large number of industries. MOCA forms from few percent up to 100 % of their business. They typically use 0.1 to 12 tonnes of MOCA per year and are most likely micro or small sized companies.
  2. **Specialists**, producing a large quantity of specific products, serving specific industries. MOCA forms 80 – 100 % of their business. They are most likely small- to medium-sized companies and use approximately 7 – 80 tonnes of MOCA per year. Their portfolios vary, but they generally supply within one or two industry sectors or product groups, i.e. small (up to 30%), medium (up to 20%) and larger (50 – 85 %) products.
  3. **Mixed** moulders, having mixed characteristics of both, generalised and specialised moulders. MOCA makes up 30 - 95% of their business. 80% of this group of moulders produce small (10 – 35%), medium (25 – 40%) and large products (60 – 75%), 20% produce only small products. They use between 6 – 40 tonnes of MOCA per year and are either small- or medium sized enterprises.

  The applicant states that approximately 20% of moulders, representing nearly 65% of the tonnage used within the supply chain responded to their survey. In their responses, the majority of moulders stated that the immediate removal of MOCA from the EEA market will have a huge impact on their ability to continue business. They stated that for their specific products no alternative (substance and/or technology/system) could replace MOCA in the medium to long term and that in case of a non-use scenario, they would, either, need to close or relocate their business. In their view, the moulding skills and know-how that was built-up over many decades in Europe would be lost. According to the survey carried out by the applicant, three possible responses to the NUS would occur:

1. **Replacing MOCA** with (a) a less suitable alternative/s or system/s leading to a partial loss of business
2. **Relocation** of production outside the EEA or **shut-down** of business
3. **Mix** of replacing, relocation and shut down

The distribution of moulders by non-use scenario and moulder type is given in Table 14 below:

Table 14: Distribution of moulders by non-use scenario and moulder type (taken from the AfA)

Moulder type	Worse alternative	Relocation or shutdown	Mix of the two	Total
Generalist	45 %	0 %	15 %	60 %
Specialist	5 %	10 %	0 %	15 %
Mixed	5 %	10 %	10 %	25 %
Total	55 %	20 %	25 %	100 %

From the table above it becomes clear that in case of the NUS:

- 55% of moulders would choose a less suitable alternative,
- 20% would need to relocate their business outside the EEA or shut-down their facilities,
- and 25 % stated that it is not yet clear what they would do in case of not granting an authorisation to MOCA, i.e. they would either replace MOCA by a less suitable alternative, relocate or shut-down.

Furthermore it becomes clear, that for the generalists, a switch to a less suitable alternative seems to be “easier” than for specialist and mixed moulders. Moreover, the applicant again highlights in his analysis of the NUS that most companies in level 2 of the supply chain are SMEs and that those are specifically vulnerable to the expected negative economic impacts of the NUS, as they have a rather low level of turnover and EBIT (earnings before interest and taxes) as well as a low number of employees.

In summary, the NUS described by the applicant and its respective impacts are listed in Table 15 below.

Table 15: Summary of the non-use scenario and its impacts (taken from the AfA)

The non-use scenario	Impacts of the non-use scenario
System provider / distributor are in a position to supply alternative chain extenders/curing agents to their cast PU customers. Qualitative argument.	– Possible loss of contracts / customers – Possible short term net revenue reduction + Decreased human health risk from not having any MOCA exposure for those system providers where there is potential exposure
Replacing MOCA with an alternative(s) or systems	– Lower quality with an alternative – Possible new machinery cost – Reduced net revenue – **Lost jobs** – Reduced value adding capability + Possible decrease in human health risk from not having any MOCA exposure
Relocation outside the EEA or production site shut down	– Relocation or shut down cost – Reduced net revenue – **Lost jobs** – Reduced value adding capability + Decreased human health risk to workers within the EEA from not having any MOCA exposure
Mix of replacing MOCA with the best available alternative and relocating production with MOCA outside the EEA or facility shut down	– Lower quality with an alternative and relocation of the facility – New machinery and/or relocation cost – Reduced net revenue – **Lost jobs** – Reduced value adding capability + Possible decrease in human health risk from not having any MOCA exposure
End user	– Higher price – Lower quality

Benefits of continued use:

Impacts for the **applicant (Suhzou)** and **distributors/system providers are** only qualitatively described. For both, the supplier of MOCA and level 1 companies, a positive impact is expected in case the authorisation is granted, as they can continue to supply MOCA to their customers in the supply chain. However, no major negative economic impact is expected in case of the NUS: as already mentioned above, Suzhou claims it is possible to adjust sales of MOCA to customers outside of the EEA, where the use of MOCA is allowed and from where European customers can source (small and medium sized) parts. Furthermore, Suzhou currently also supplies alternative curing agents/chain extenders to its EEA customer and they are expected to do so also for those moulders who decide to switch to a less suitable alternative in case the authorisation is not granted. For the 5

companies in level 1 of the supply chain, i.e. distributors and system providers, also only a minor negative impact is expected as they do not solely rely on MOCA-sales. As a consequence, any initial loss of business is expected to be offset by providing technical knowledge of alternative technologies to moulders.

Impacts for **moulders** (level 2 companies, a total of 89) as well as **further affected actors** (such as supporting industries and the public) are summarised by the applicant as follows from the table below.

Table 16: Quantified impacts of the non-use scenario for moulders and other affected actors (taken from the applicant's responses to SEAC's question)

		Benefits of continued use	**Comment from the applicant**
Moulders	Value added lost, based on expected job losses	€3.9 – 15.5 million	388 jobs lost, monetised to value added to society
	Machinery and relocation costs	€15.1 – 121.6 million	Machinery & relocation
Supporting industries	Indirect impact	€19.9 million	IP/OP model (485 workers)
Public/lost consumption	Direct	€2.9 million	388 workers' lost consumption
	Indirect	€3.6 million	IP/OP model (485 workers' lost consumption)

In order to perform the above analyses, which are all based on job losses (except the evaluation of machinery and relocation costs), the applicant performed an extrapolation of lost jobs in order to cover Suzhou's whole supply chain. Only those downstream users that are not expected to be able to substitute MOCA (by an inferior alternative) are covered. The extrapolation is based on the type of moulder (generalists, specialists, mixed), the product size (small, medium, large) and on feedback on job losses received from moulders through the questionnaires. These lost jobs were, together with tonnages of MOCA used, allocated to moulders' type and products' size based on substitution possibilities. In summary, based on feedback received, there would be 41 jobs lost among specialist moulders, 75 among mixed moulders and 202 among generalists due to the inability to substitute MOCA. These companies are using a total of 354 tonnes MOCA per year. As this figure does not consider the overall MOCA-supply chain (Suzhou supplies approximately 516 tonnes MOCA per year to the EEA), an extrapolation was performed by the applicant. This extrapolation leads to a total of 60 jobs lost among specialists, 109 jobs lost among mixed moulders and 219 jobs lost among generalists in the supply chain of Suzhou, which sums up to **388 lost jobs** in total for moulders that cannot substitute MOCA. This figure forms the basis for the applicant's analyses of the benefits of continued use.

- Impact on moulders (1) (lost value added): the loss of value added in the EEA due to the non-use scenario is calculated by using the value added-to-total job ratio derived from Eurostat's input-output tables[1]. The tables divide the European economy into 74 industries and are based on NACE Rev. 2 (Statistical classification of economic activities in the European Community[2]); latest data is available from the year 2011. The applicant concludes that the division "Manufacture of rubber and plastic products", including a group called "Manufacture of plastic products" (NACE 22.2), describes the MOCA industry best. This group comprises the processing of new or spent (recycled) plastic resins into intermediate or final products, using processes such as compression moulding, extrusion moulding, injection moulding, blow moulding and casting. For most of these groups, the production process is such that a wide variety of products can be made. Therefore, according to the applicant, the use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production clearly falls into this category, even though the cast PU industry is just a small part of the "Rubber and plastic products" industry. As a consequence, the applicant chose to use the multiplier of this category to describe the effects in the cast PU industry.
  Those moulders who stated that they are able to substitute (by an inferior alternative) are, according to the applicant, excluded from the value added loss calculation. Applied to the figure of 388 lost jobs (calculated as described above), the value added-to-total jobs ratio for "Rubber and plastic products" of 0.05008[3] gives an overall monetised value of €19 million of lost value added due to a non-use of MOCA. Furthermore, the applicant did consider the average duration of unemployment of men in OECD countries (as the rubber and plastic products industry is very male-dominated and all of the mentioned countries are OECD countries) which is 9.3 months (2005 – 2014)[4]. Finally, the derived figure was price adjusted to 2014 prices, which are the latest available data via Eurostat. The applicant calculates a total of **€15.5 million** which is regarded being the **direct negative economic impact** in case the authorisation of the use of MOCA is not granted. During SEAC's opinion making process, the applicant provided further details of the calculations i.e. Excel spreadsheets in order for SEAC to verify the results and a sensitivity check on the above derived negative economic impact as the Rubber and plastics industry is claimed to be very generic and include figures from large companies, whereas this application for authorisation mainly covers SMEs. Based on the assumption that in an industry, approximately the best 20% of companies make 80% of profits/value added of the industry and vice versa, the applicant assumed that workers covered by this application for authorisation make approximately 25% of the industry's average profit/value added, leading to a direct negative economic impact of **€3.9 million** for the lower bound.

- Impact on moulders (2) (machinery & relocation costs): according to the applicant, potential machinery and relocation costs vary between €150,000 and €300,000 per moulder for replacing existing machinery to new machinery and between €250,000

[1] http://ec.europa.eu/eurostat/web/esa-supply-use-input-tables/data/database
[2] http://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF
[3] Rubber and plastic industry value added / rubber and plastic industry employment, based on Eurostat's Input-Output tables: http://ec.europa.eu/eurstat/web/esa-supply-use-input-tables/data/database
[4] OECD: http://stats.oecd.org/

and €3,000,000 per company for relocation. The applicant states that these costs are speculative and range widely. Furthermore, there might be benefits to other actors from these costs, so they were initially not included in the applicant's cost-benefit calculation but provided only later due to SEAC's request for any indication on substitution costs, as the applicant stated that some moulders affected will possibly substitute MOCA by a less suitable alternative. With the above values and an estimation of 55% of moulders changing to a less suitable alternative, 20% of moulders relocating outside the EEA or shutting down their business and 25% combining both (based on feedback received via questionnaires), the total costs sum up to **€15.1 – 121.6 million for relocation and machinery.**

- Impact on moulders (3) (permanent market loss): the applicant further states that changing to a less suitable alternative (substance and/or system/technology) would lead to a permanent market share loss for moulders (associated with reduced net revenue) and that a non-full recovery of such a loss is expected. With MOCA, the applicant explained that the moulders have two current competitive advantages: the quality vs. price ratio that has already been presented above in section 7.2, and the "closeness to customers". The closeness to customers refers to cases, such as coating of large items, for which there is difficulty in transporting the item (e.g. the large roller used in stainless steel industry). On the other hand, the closeness to customers also refers to long-lasting customer relationships which have been developed over many years and which places imported goods at a disadvantage. However, according to the applicant, if moulders in Europe are forced to change to a less suitable alternative, the quality vs. price ratio will drop. This might make the argument for changing to imported goods stronger, despite the long lasting customer relationship. In addition, technical requirements may not be met with customers that require on-site casting. As has already been described in section 7 above, moulders state that, given time, they can develop new optimized solutions with less suitable alternatives so that the quality vs. price ratio could possibly be improved, especially for smaller parts. However, the strategic advantage related to closeness to customers might be lost more or less permanently because if there is a gap in the market for some period of time, the end customers might find other solutions. By the time the newly optimized solution is found by moulders within the EU, their service may no longer be needed. The strategic advantage based on long-lasting customer relationships is expected to be lost permanently by the applicant because the time in between may give the competitors outside EEA the time to build their own customer relationships. This is the reason why the applicant considers that the market will not fully recover in the long term. Nevertheless, this permanent market loss has not been quantified by the applicant.

- Indirect impact on supporting industries in Europe (indirect value added lost): in addition to the 388 direct jobs lost for moulders, the applicant also assessed indirect impacts for supporting industries due to indirect jobs losses, that is interpreted as a wider economic impact and assessed via IP-OP methodology (details on the calculation are claimed confidential, but were made available to SEAC). The number of indirect jobs expected to be lost by supporting industries (amounting to 485) is first calculated from the direct job losses multiplied by the direct effect employment multiplier of 2.251[5] (giving the expected total unemployment figure). Then the

[5] Final demand employment multiplier / direct employment coefficient

monetisation of the lost value added due to these indirect jobs losses is calculated based on the value added-to-total job ratio for "all industries" of 0.05055[6] (also derived from Eurostat's input-output tables) leading to an (unemployment-duration and price adjusted) indirect impact or indirect value added lost for supporting industries of **€19.9 million**.

- Social Impacts / Impacts on the public (lost consumption): according to the above, the non-use scenario would be associated with 388 direct jobs losses and 485 indirect jobs losses. The applicant then valued the economic consequence of this unemployment effect through the reduced consumption due to salary loss. Both direct and indirect social impacts are evaluated based on the income lost during the unemployment duration (being again 9.3 months), a share of consumption lost assumed to be 70% of the salary and 50% of employment allowances. This latter wasn't initially part of the applicant's assessment but was included during the opinion making process on SEAC's request in order to use more "realistic" assumptions as regards unemployment. Based on these assumptions, the total reduced consumption is estimated at **€2.9 million for direct jobs losses** and **at €3.6 million for indirect jobs losses.**

Conclusion

Applicant's conclusion on benefits and costs of continued use:

According to the applicant, the benefits of continued use of MOCA as a curing agent/chain extender in the cast polyurethane elastomer production clearly outweigh the risks to human health. The applicant's conclusion is given in table 17 below, which includes several adaptations made by the applicant during the opinion development process.

[6] All industries' value added in total / All industries' employment in total, http://ec.europa.eu/eurostat/web/esa-supply-use-input-tables/data/database

Table 17: Applicant's conclusion on benefits and risks of continued use of MOCA (taken from the applicant's response to SEAC's questions)[7]

Distributional analysis		Benefit of continued use	Cost of continued use	Comment
Applicant/supplier		+	0	
Distributors		+	0	
System provider		+	0	
Moulders	direct impact 1	EUR 3.9-15.5 M	0	388 jobs lost monetised to value added to society
	direct impact 2	EUR 15.1-121.6 M	0	Machinery & relocation
Supporting industries	indirect	EUR 19.9 M	0	Via IO-calculation (485 workers)
Public / lost consumption	direct	EUR 2.9 M	0	388 workers' lost consumption
	indirect	EUR 3.6 M	0	Via IO-calculation (485 workers' lost consumption)
	Health	0	EUR 0.7-1.2 M	
Conclusion	Direct	EUR 21.9-140 M		
	Indirect	EUR 23.5 M		
	Total	EUR 45.4-163.5 M	EUR 1.1-1.8 M	Clear benefit in continued use scenario

SEAC's conclusion on benefits and costs of continued use:

Costs of continued use:

Regarding the human health impact assessment, SEAC agrees to the applicant's approach. During the opinion making process, the assessment was adjusted by the applicant and RAC and SEAC as pointed out in the section above. No sensitivity check was performed by the applicant. However, SEAC regards the assumptions taken and the approach followed as robust:

- ➔ Potential workers (213) exposed were taken into consideration;
- ➔ Population exposed via environment, both, locally and regionally, was taken into consideration;

[7] Note to the reader: this table is taken from the applicant's responses to SEAC's questions. As can be clearly seen from the table, it contains an error in the summation of the total costs of continued use, which should correctly read €0.7 – 1.2 M instead of €1.1 – 1.8 M.

- ➔ RAC's dose-response relationship was used by the applicant; wrongly calculated fatal and non-fatal cancer cases were corrected by SEAC;
- ➔ RAC adjusted the exposure estimates for both, manual and automatic moulding; these estimates were further used by SEAC to adapt the human health impact assessment accordingly;
- ➔ The values used for monetisation of human health impacts were taken from ECHA's report "Valuing Selected Health Impacts of Chemicals: Summary of the Results and a Critical Review of the ECHA Study" (December 2015, ECHA), taking into account recently developed VSL between €3.5 million (lower bound) and €5 million (upper bound), discount rates between 2% and 4% and a latency period of 10 years.

The monetised human health impacts range from **€0.53 million to €0.87 million** and are slightly lower than the originally calculated values by the applicant (€0.7 to €1.2 million). This is due to the incorrectly calculated fatal/non-fatal cancer cases by the applicant, which overestimates the fatal cancer cases. Overall, SEAC concurs with the methodology used to perform the human health impact assessment following the SEA guidance and is of the view that it is consistent with existing practice in authorisation applications.

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

Non-use scenario:

The non-use scenario is based on responses of affected actors (system providers, distributers and moulders) in the supply chain to the survey carried out by the applicant via telephone interviews and questionnaires. Still, uncertainties exist: only ~20% of moulders responded to the survey performed by the applicant. Although these are representing approximately 65% of the tonnage used within the supply chain, the representativeness of the feedback in regard to the non-use scenario remains somewhat questionable. Furthermore, even though the assumptions made by the applicant sound logic and credible, SEAC is not able to verify the details, e.g. the share of moulders that are claimed to switch to an alternative, to relocate or shut-down business. Moreover, 25% of moulders responded that they are not sure yet how their response to a non-use of MOCA would be. Overall, while expressing some reservation regarding the defined NUS due to the above stated uncertainties, and in absence of any other information on possible reactions of affected actors, **SEAC agree that the defined NUS can be used further for the analysis of the benefits of continued use** of MOCA due to the following reasons:

- ➔ The non-use scenario is transparently described, i.e. the applicant explains the possible consequences in the supply chain, such as expressed directly by different actors themselves, i.e. for the applicant/manufacturer of MOCA (=Suzhou), system providers and distributors of MOCA (level 1 companies) and moulders (level 2 companies);
- ➔ The different possible responses expected from level 2 of the supply chain reflect the variety of different moulders and their possibilities to react to potential changes (specialists, generalists, mixed moulders, producing a huge variety of different products/product parts);
- ➔ Extensive discussions on the non-use scenario have taken place between SEAC and the applicant during the opinion-making process, clarifying parts of SEAC's initial uncertainties of the non-use scenario (e.g. clarifications were provided how the questionnaires have been developed, how the telephone interviews have been

performed, an affected moulder company joined the trialogue in order to explain their situation in case of a non-use scenario, etc.);

➔ It has been clarified to SEAC that the supply chain mainly consists of SMEs, which limits the possibilities of companies to react/adapt to a change in market conditions.

Benefits of continued use:

SEAC does not regard the applicant's approach for assessing the negative economic impacts of not granting an authorisation and the welfare loss to society respectively as fully appropriate, which gives rise to uncertainty. The reasoning of SEAC's concern is summarised as follows:

- Impacts on moulders (1): this part of the applicant's assessment is considered by SEAC as transparent and clearly presented in the application for authorisation; calculation spreadsheets have been provided to SEAC and adaptations have been made in order to derive the lower bound of expected impacts. However, in SEAC's view, the methodology used by the applicant is not regarded being fully appropriate: instead of assessing the lost value added (based on expected job losses and EUROSTAT data about the Rubber and Plastics industry's average value added per employee) as the main negative (economic) impact of not granting an authorisation, e.g. expected profit losses to moulders could have been assessed. SEAC considers evaluations based on profit and revenue losses being more appropriate for assessing net welfare impacts to society than evaluations based on the value added lost and job losses. In general SEAC certainly notes the dimension of unemployment effects. However, these effects, arising from the closure or relocation of a company, have merely distributional consequences at the societal level. To this respect, further guidance about impacts to be assessed in a socio-economic analysis in authorisation applications is available through ECHA's guidance on SEA[8]. SEAC was informed by the applicant that moulders were reluctant to share their profit and revenue information in detail. Therefore the applicant was inclined to use the moulders' job loss estimations and the data available (e.g. industry specific information from Eurostat, as explained above), rather than draw any extrapolation, estimation and conclusions based on scarce data. Whilst SEAC notes the difficulties encountered by the applicant in receiving sensitive information on e.g. profits from the supply chain's actors, it stresses that also the applicant's approach is based on estimations and extrapolations which contain substantial uncertainties (such as the actual number of moulders affected by closure or relocation of their business and the corresponding actual number of employees losing their job as well as the appropriateness of multipliers used) and are questionable from a representativeness point of view (low share of moulders responding to questionnaires). Moreover, SEAC regards the approach taken by the applicant to rather overestimate the direct economic impacts of not granting an authorisation for the use of MOCA, which is contradicting the applicant's statement of having taken a conservative approach as using added value lost as a measure of economic impact tends to overestimate the benefits of continued use. Nevertheless, SEAC agrees to take these monetised impacts further in the cost-benefit analysis as the applicant agreed during the opinion making process of SEAC

[8] https://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

to perform a sensitivity check, which provides SEAC additionally with a lower bound of expected impacts.

- Impact on moulders (2): the information on machinery and relocation costs is claimed to be highly speculative by the applicant himself. SEAC agrees to this view. Furthermore, according to SEAC, the calculations made are not presented transparently and only a rough calculation multiplying figures that haven't been substantiated (e.g. relocation costs between €250,000 and €3 million) by the number of companies affected was provided to SEAC. Although SEAC acknowledges that in case of not granting an authorisation, costs due to the purchase of new machinery and relocation will arise, it cannot agree to include these unsubstantiated cost figures in the overall monetised figure of the benefits of continued use of MOCA.

- Impact on moulders (3): as presented above, the applicant states that changing to a less suitable alternative would lead to a permanent market share loss for moulders associated with reduced closeness to customers and loss of long-lasting relationships. SEAC considers this impact as plausible. However, this impact has not been quantified by the applicant and therefore was not included in the overall monetisation.

- Further direct and indirect impacts on supporting industries in Europe/social impacts: for calculating the impacts on supporting industries and the public (lost consumption), an IP/OP approach (claimed confidential by the applicant) was used. These calculations are again based on expected job losses due to the non-use scenario and the reasons why SEAC does not regard this approach being fully appropriate are given above. For the IP/OP methodology, SEAC stresses that the guidance on SEA (as mentioned above) clearly states that macro-economic modelling, like IP/OP modelling, is *"less likely to be relevant"* for a SEA. Such modelling would be more relevant in cases where economic impacts are expected to affect all sectors of the economy in a significant way. In the absence of any supportive information provided by the applicant, this is not regarded being likely by SEAC for this application for authorisation. Furthermore, impacts derived by IP/OP modelling are not necessarily net changes in economic welfare arising from the policy change being considered.

With the above described calculation, the applicant arrives at monetised benefits of continued use of MOCA between **€45.4 million** to **€163.5 million.** These monetised figures are higher than originally calculated by the applicant (€39.8 million). The difference is mainly due to SEAC's requests about refining the evaluation on several impacts (sensitivity check), in particular concerning the added value lost for moulders, as well as providing information on possible substitution and relocation costs considerations. However, for the latter, SEAC didn't suggest and does not agree to add these monetised impacts to the overall monetised benefits assessment for the reasons already set forth above. Therefore SEAC does not regard this updated performed assessment as better reflecting the overall monetised benefits of the non-use scenario. Whilst SEAC does not agree to sum up the different monetised impacts and expresses some reservation towards them, SEAC agrees that the information provided can still be used for a comparison with the calculated human

health impacts. SEAC notes that already each of the different calculated monetised benefits of continued use of MOCA outweighs the risks to human health.

SEAC's conclusion on costs and benefits:

For drawing a conclusion on whether the benefits of continued use of MOCA have been adequately shown to exceed the risks, SEAC takes note of the following information:

- The RAC and SEAC adjusted monetised health impacts range between **€0.53 million and €0.87 million**, these are calculated over the requested review period of 12 years
- The direct economic impact to moulders (value added lost) is expected to be between **€3.9 million and €15.5 million**, calculated based on estimated job losses (extrapolated on basis of feedback of moulders) and value added-to-total jobs ratio for the "Rubber and plastics industries", calculated for the average duration of unemployment for men in OECD countries of 9.3 months
- Information on further **quantified negative impacts of the non-use scenario**, such as
  -> machinery and relocation costs to be borne by moulders (€15.1 to €121.6 million)
  -> negative economic impacts for supporting industries, calculated via IP/OP analysis (€19.9 million)
  -> social impacts due to job losses (lost consumption, €2.9 million direct and €3.6 million indirect)
- Other **negative impacts** described qualitatively such as a permanent market loss for moulders due to the switching to a less suitable alternative

In SEAC's view the above values and information allow a comparison of the expected benefits of continued use of MOCA to the expected risks to human health. Whilst SEAC does not agree to generate an overall monetised value of all the single negative effects assessed by the applicant, SEAC regards the calculation of direct economic impacts (1) on moulders (value added lost based on job losses) as being probably the most appropriate parameter (though uncertain) to compare those to the costs of continued use as these impacts are based on direct feedback received from moulders. Furthermore, this impact has been subject to a sensitivity check. Therefore, SEAC agrees to use this figure for a comparison with the monetised human health impacts and notes that this benefit clearly outweighs the risks to human health. Regarding further (qualitative and quantitative/monetised) impacts, even though the quantification and monetisation are uncertain, SEAC acknowledges that such impacts will most probably occur. SEAC regards those to be an important piece of information as they serve as an additional margin of safety for concluding on whether the benefits of the continued use are expected to exceed the risks.

As a result, SEAC supports the conclusion of the applicant's assessment, that the benefits of continued use of MOCA outweigh the risks to human health.

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation:

The applicant shall communicate to the downstream users via exposure scenarios the following requirements

Automatic moulding process:

- Automation and containment of the moulding process, including a glove box for the loading of MOCA, automatic transfer of MOCA to the reactor and an enclosed system for the melting and mixing phase can be considered to represent good practice and whenever practicable shall be adopted.
- A regular cleaning and maintenance program of the glove box, including the structural integrity of the gloves shall be implemented to eliminate the potential for dermal exposure.
- All of the aforementioned exposure control/containment measures shall be fitted with extraction ventilation (LEV), unless it can be shown (by measurements) that emissions to the air are negligible.
- Similarly. LEV shall be in place to reduce exposure during loading and sampling activities, as well as during the dispensing and moulding phases Curing ovens shall be equipped with extraction.
- Regular maintenance program of the mechanical extraction ventilation system shall be implemented, including frequent checking of air velocity by e.g. smoke tube and annual throughout testing of the effective and correct function of the system.
- Appropriate working clothing (with long sleeves) and chemical resistant gloves shall be used in all tasks involving the use of MOCA, including the loading phase. In maintenance or cleaning of large spills, full body PPE, e.g. Tyvek, should be worn.

Manual moulding process:

- In manual moulding, LEV (e.g. partially enclosed extraction booth or fume cupboard) shall be applied when MOCA pellets are loaded from the drums to the melter. Melting shall be done in an enclosed system with extraction. Mixing step shall include LEV, and it shall be done using automatic stirrer to prevent close contact and exposure of worker due to splashes.
- Regular maintenance program of the mechanical extraction ventilation system shall be implemented, including frequent checking of air velocity by e.g. smoke tube and annual throughout testing of the effective and correct function of the system.
- The dispensing and moulding phases and curing ovens shall be equipped with local extraction.
- Appropriate working clothing (jacket with long sleeves or coveralls) and inner chemical (MOCA) resistant gloves together with outer (e.g. heat resistant) gloves shall be used in all tasks involving the use of MOCA. In maintenance or cleaning of large spills, full body PPE, e.g. Tyvek, should be worn.
- When MOCA is moved from one place to another (WCS2; moving melted MOCA to mixing area) closed containers shall be always used.

Training and general housekeeping practises (both automatic and manual process):

- Workers shall be regularly (at least yearly) trained in the proper use of PPE, including the frequent change of gloves, the correct removal of contaminated gloves and proper storage of gloves and RPE, as well as fit-testing and maintenance of RPE. RPE shall be used as described in WCSs. Supervision shall be provided to ensure availability, correct use and maintenance of all PPE.
- Procedures that would address good housekeeping shall be implemented by all users of MOCA. Any spillages of MOCA or PU mixture shall be cleaned immediately using appropriate cleaning methods. Following each batch, cleaning of work surfaces, which may contain traces of MOCA, shall be performed to prevent build-up of MOCA. Also, other general good industrial hygiene practices shall be applied, including the prevention of the areas in which MOCA is used should be strictly segregated from other activities and the access limited to trained personnel. Training and supervision shall be provided to ensure adherence to all procedures.
- Any containers of MOCA shall be closed and stored in a designated area suitable for the storage of dangerous chemicals.

Monitoring activities (both automatic and manual moulding)

- Exposure of all workers working within the premises in which MOCA is used shall be followed by twice yearly biomonitoring programmes, in which urinary total MOCA levels are measured. If urinary levels are repeatedly low (below LoD), frequency of monitoring may be reduced.
- Measurement of surface contamination shall be conducted in order to identify exposure sources and prevent exposure via the contaminated surfaces. This is especially important when biomonitoring shows measurable (above LoD) urinary MOCA levels. If urinary levels consistently show urinary levels below LOD, surface monitoring may not be needed.
- The information gathered in the monitoring campaigns shall be used by the applicant to review and improve the risk management measures (RMMs) and operational conditions (OCs) to further reduce workers' exposure to MOCA. The outcomes and conclusions of this review, including those related to the implementation of any additional RMMs, must be documented. The results of the monitoring and of the review of the OCs and RMMs shall be maintained, be available to national enforcement authorities and included in any subsequent authorisation review report submitted.
- Wipe and powdering tests of representative samples (i.e. dependent on the production volume) of end-products shall be performed to ensure that the levels of MOCA in the final product are below classification concentration cut-off limit of 0.1 % w/w.

Prevention of environmental emissions:

- Regarding environmental emissions, LEV filters/scrubbers shall be used to minimize air emissions. In order to prevent any waste water releases washing of empty containers shall be prohibited.

AND

Description of conditions and monitoring arrangements for review reports:

- In case the applicant submits a review report, or DUs submit further authorisation applications, a more precise name and description of the use applied for, and a more specific (narrow) scope of the use applied for is requested, in terms of the different articles/parts manufactured.

Justification:

RAC considers that RMMs and OCs described in the application are not appropriate and effective in limiting the risk to workers and the general population, due to the broad scope of the application, which describes a wide variety of work practices and RMMs. Although risk characterisation is performed on the basis of biomonitoring data, the applicant has not been able to define minimum standards for OCs and RMMs, which should be in place in order to achieve the exposure levels described. Instead, the applicant has tried to cover also practices which clearly do not represent best practic in the field and which are not fully substantiated by the measurement data. The proposed minimum conditions are intended not to support such practices in the future.Therefore, RAC has defined minimum standards for OCs and RMMs, which shall be in place in order to achieve the exposure levels described. These minimum standards are based on the general principles of hierarchy of control, examples of the best practises in the supply chain and literature on the safe handling of MOCA.

Good general housekeeping practices, regular monitoring of exposure, training and good individual working practices have a significant role in the management of exposure to MOCA. Although the applicant has provided good examples from some individual companies, it is not evident that these good practices are applied at all sites using MOCA. In the contributing scenarios these practises have been described only at the very general level or are not given as mandatory conditions (e.g. monitoring activities). In order to ensure that these will be applied in all companies these are given as RAC additional conditions.

Regardless of whether the process is automated or manual, the moulding and curing phases are not closed but typically include the use of LEVs. However, manual moulding includes a higher potential for spillages and contamination of surfaces, with resulting risk of dermal exposure, when compared to automatic moulding. Therefore, automated moulding with enclosed systems shall be applied whenever practicable.

There are also concerns related to the MOCA residues in the end-products and although some companies have performed wipe and powdering tests to ensure safe use of the products downstream, this has not been a common practise in all companies. The additional condition above is meant to ensure that this will be done by all companies.

The air extracted through used LEV is in many cases released to the atmosphere with no removal of contamination with MOCA at a proportion of location. Some downstream users might perform washing of the empty containers, the condition above shall ensure that any waste water release is prevented.

SEAC has concerns that the scope of this application for authorisation is broad, which gives rise to uncertainty when assessing and concluding on the (technical and economic) feasibility of alternatives, hence SEAC proposes the aforementioned condition for the review report.

10. Proposed review period:

☐ Normal (7 years)

☐ Long (12 years)

☒ Short (4 years)

☐ Other:

Justification:

Applicant's justification for a 12 year review period

As summarized in the application for authorisation, the applicant's request for a 12 year review period is based on the following arguments:

- it would provide a more stable business environment for the micro-, small- and medium-sized enterprises to operate in, while searching for alternatives, develop recipes and formulations and replace MOCA;
- it would provide sufficient time for moulders to substitute MOCA with suitable alternatives in a manner that meets the requirements and expectations of their customers as well as allowing the end users to trial pieces made with alternatives in the working environment;
- it would enable the micro-, small- and medium-sized moulders to spread any costs to change (e.g. moulds and machinery, etc.) over a longer period of time and thus have a lower overall impact on their business;
- it would allow enough time such that the moulders can become familiar with and perfect processes with alternative reagents;
- it would allow the moulding companies to phase in alternatives on different product lines, starting with those that are more easily to be replaced. This will result in gradual reduction of MOCA use, as already initiated by 45% of moulders before MOCA's inclusion in Annex XIV of the REACH Regulation.

During the opinion-making process, the length of the review period has been extensively discussed between the applicant, third parties and SEAC. The applicant argued that his request for a 12 year review period was derived from the responses to his survey where 20% of the moulders requested 4 years, 10% requested 7 years and 60% requested 12 years. From these responses, the applicant attempted to find a compromise timeframe that was based on estimates of not being any technical issues encountered with product development for all products/product parts made within all the different industry sectors covered by this authorisation application. Referring to the comments received during the public consultation about the possibility of already substituting certain products and products parts by the sunset date, the applicant confirmed that some issues with alternatives can be overcome with some products and product parts, especially the smaller ones, before the 12 years review period already. A long review period however would be needed for large articles (exceeding 100 kg) because R&D efforts are showing that the development of an alternative could not be available within a normal review period. However, a third party stated during the trialogue, that product size is not the appropriate criteria for the substitution timeframe, but rather product-specific requirements. In any case, irrespectively of the products size, the applicant stated that due to the volume of products manufactured, a review period of a minimum of 4 years is required to ensure transition even for small products/product parts. During the opinion-making process, the

applicant considered that a phased substitution might be possible, therefore he suggested a staged review period, following the schedule below:

- a review period of 12 years is granted for articles with a weight > 100 kg, for any articles that can demonstrate the need of high dynamic performance that can't be fulfilled with alternative curative agents or alternative polyurethane systems and for any articles that are used in Oil & Gas, Aviation or Watch industries where guarantee for a long product lifetime and/or good heat aging properties,
- a review period of 7 years is granted for articles with a weight between 10 and 100 kg and the articles are considered commodity products;
- a review period of 4 years is granted for articles with a weight below 10 kg, and the articles considered commodity products,

The applicant could not elaborate the above categorisation in a realistic and meaningful manner and hence decided not to pursue this approach further. SEAC recognises this being a further indication that substitution is ongoing already and might be easier/quicker for certain types of products covered by the broad scope compared to others. However, first of all SEAC is not in the position to design and propose a staged review period as this would in essence modify the applicant's use description by splitting the use in a new manner. Secondly, even if SEAC would in principle be willing to recommend a staged review period it simply has not sufficient objective information at hand that would make such a suggestion possible. The applicant further substantiated his argumentation for a 12 years review period based on additional inputs obtained from 2 additional surveys carried out in his supply chain. The outcome of these surveys emphasized that 12 years, as originally requested by the applicant, are the necessary timeframe for substitution on the grounds that moulders do not have a technical solution for a significant percentage of the value of their products currently moulded with MOCA.

Additionally to the abovementioned arguments from the applicant, SEAC took note of the following considerations: RAC's advice to SEAC, the possibility to substitute in view of the wide scope of the use applied for, and the assessed socio-economic impacts.

RAC's advice:

There are uncertainties related to the OCs and RMMs described in the application, since all of the practices do not represent the best practices in the field and are not substantiated by the available measurement data. These uncertainties have been addressed by the conditions set by RAC. However, since the management of exposure and risks of MOCA rely largely on personal protection and good individual working practices, regular monitoring of exposure, review and improvement of OCs and RMMs are essential in order to minimize the risks. The RAC rapporteur therefore advises SEAC to r*ecommend a review period of no longer than 7 years*.

Substitution considerations:

As presented above, the applicant performed its assessment based on a **12 years review period.** The applicant's reasoning for requesting 12 years as well as SEAC's assessment is given in the respective sections of this opinion. The 12 years review period reflects the long review period of ECHA. SEAC agrees with the applicant's conclusion that currently, an *overall*

technically feasible alternative for the use of MOCA as a curing agent/chain extender in the cast polyurethane elastomer production does not seem to exist. However the broad scope of the use applied for gives rise to substantial uncertainty as regards the feasibility of substitution. Specifically the applicant's conclusion that a significant percentage of the value of the products currently moulded with MOCA has no technical solution for substitution implies, that there is in fact a proportion of uses where substitution is regarded being technically feasible already (figures claimed confidential by the applicant). Therefore SEAC find it likely that the application for authorisation covers applications where substitution is already feasible or will become so in short-term. Moreover, this is regarded as being likely by SEAC due to several types of information provided to SEAC during the opinion development process by the applicant and third parties. For instance, 80% of the EU cast polyurethane production has already phased-out MOCA based technologies, the applicant confirmed that substitution is ongoing already, third parties claimed to be convinced that for all applications covered by this authorisation application, substitution is possible and feasible already to date, etc. (for further details, see section 7.2. of this opinion). Therefore, SEAC find it likely that the scope as defined within this application for authorisation covers products/product parts and industries, where substitution is feasible already by the sunset date or before the 12 years that were requested by the applicant for setting the review period.

Socio-economic considerations:

- **Benefits of continued use:** SEAC agrees that the applicant's approach to assessing the benefits of continued use of MOCA is sufficient to conclude that these are - in spite of the remaining uncertainties such as explained in section 8 - significant and will allow a comparison with the health impacts. During the opinion making process, the assessment was further adjusted by the applicant on request of SEAC and a sensitivity check was performed on parts of the impacts by the applicant, in particular on the direct economic impacts, in order to mitigate some of the identified uncertainties. SEAC and even the applicant considers some of the quantified impacts assessed as being too speculative to include them into the overall monetised impacts, e.g. the estimates on machinery replacement and relocation costs. Nevertheless, these impacts are still valuable information for SEAC and serve as an additional margin of safety for SEAC's interpretation of the comparison between costs and benefits. Overall and although uncertainties remain, SEAC regards the approach taken for the benefits assessment as appropriate to compare them to the human health impacts.

- **Risks of continued use / impacts to human health:** SEAC agrees to the approach taken and the methodology used by the applicant for the assessment of impacts to human health. SEAC's reasoning is given in section 8 above.

- **Risk / benefit comparison:** with the information (both, qualitatively and quantitatively) available in the authorisation application, provided during the opinion making process by the applicant and submitted during the public consultation, SEAC agrees to the applicant's conclusion, that the benefits of continued use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production outweigh the risks to human health.

SEAC's conclusion on the recommendation of the review period:

Some of the criteria for recommending a long review period[9], as requested by the applicant, could be regarded as being fulfilled for some of the industrial sectors and applications covered by this use. These criteria include MOCA being also used in sectors with high safety and qualification standards, the unlikeliness that alternatives will overall become available in the short run, and the fact that substitution is regarded as being a case-specific process (depending on product size, product type and requirements,). Nevertheless, SEAC notes that this is not the case for the full scope of this use applied for and for all industries and products/product parts covered respectively. The actual possibility to substitute some products and products' parts before the sunset date or before the requested 12 years review period has been even confirmed by the applicant. Furthermore, third parties claimed to be convinced that a solution for substitution can be found for all products/product parts by the sunset date in case the respective effort (R&D, testing trials, etc.) is taken by moulders. As a consequence, SEAC has reservations about the appropriateness of the applicant's approach and about the quality of the analysis of alternatives (too generic, not focusing on critical applications/products/product parts), specifically about the broad scope of the use for which suitable alternatives may already be available and implemented or will become so in short term. This gives rise to significant uncertainty on several aspects, i.e. the actual substitution possibilities for different industries and therefore the actual consequences for moulders and the respective actual negative economic impacts of not granting an authorisation. Still it is clear from the information given in the authorisation application and the case studies provided during the opinion-making process (claimed confidential by the applicant) that not granting an authorisation for the use of MOCA as a curing agent/chain extender in the cast polyurethane elastomer production would lead to negative economic impacts for different actors in the EEA. Moreover, due to the human health impacts of continued use being relatively low, an overall net benefit from granting the authorisation is expected even though only some of the applicant's assessed benefits of continued use of MOCA are considered by SEAC in the cost-benefit comparison.

In conclusion, taking into account:

- the applicant's argumentation regarding the time required to industrialise alternatives put forward to justify the requested review period of 12 years,
- the expected negative economic impacts of the non-use scenario for moulders and other actors, such as supporting industries,
- the expected social costs of the non-use scenario due to unemployment,
- the expected human health impacts of the continued use scenario,
- the significant uncertainties arising from the applicant's approach (mainly as regards substitution due to the broad scope, i.e. the actual possibility to substitute before the 12 years review period requested for about 30% of products/product parts covered by the use applied for, such as confirmed by the applicant),
- that the criteria for long review period have not been met,
- RAC's advice to SEAC to *recommend a review period of no longer than 7 years.*

SEAC recommends a 4 years review period.

[9] See also: https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf

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

☒ YES

☐ NO

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

☐ YES

☒ NO

☐ NOT APPLICABLE

Justification:

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

RAC's reasoning for not amending the opinion: In their comments, the applicant raised a concern on the investment required to comply with RAC's recommended conditions, which, in the opinion of the applicant, may focus the limited resources of SMEs using MOCA on compliance with the conditions, instead of R&D related to the substitution of MOCA. In addition, a concern was raised on the potential additional investment required to comply with the binding occupational limit value (OELV), which is planned to be set under Directive 2004/37/EC on Carcinogens and Mutagens at Work (CM directive).

RAC emphasizes that, while its assessment is based on the data provided by the applicant and information available related to good practices in the industry sector represented in the application, the CM directive requires the employer to assess and manage the risk related to exposure, and if it is not possible to replace the substance or to enclose the process, to reduce the exposure to a minimum (primarily by designing the work processes so as to minimize release of the substance). As explained in the justification for additional conditions, in the current application, the applicant has described also practices which clearly do not represent best practice in the field and do not follow the principle of the minimization of exposure. It should also be noted that most of the conditions given by RAC are related to the good general housekeeping practices, training and good individual working practices, which have a significant role in the management of exposure to MOCA.

If there is a binding occupational limit value (OELV) established for MOCA under the CM directive, the conditions given by RAC will help companies to comply also with this OELV. However, the cost of compliance with provisions of other legislation do not constitute an element to be taken into account by RAC.

For these reasons, RAC considers that there is no new information or evidence provided by the applicant in their recent comments that would allow a change in RAC's opinion.

SEAC's reasoning for not amending the opinion: To summarise, in his comments to RAC's and SEAC's draft opinion, the applicant states that moulders have shown a clear willingness to implement measures to limit human and environmental exposure to MOCA and further, to move away from MOCA use in products where alternatives were both, technically and economically feasible for that particular target application. The applicant

emphasises that there should be no uncertainty surrounding this commitment, which was clearly expressed by moulders to REACHLaw during the course of data gathering for this project, by moulders present at the Trialogue meeting and by 3rd parties. However, the applicant additionally emphasises that there is only limited scope for additional substitution ("additional" to those already ongoing since decades) due to technical, economic and processing deficiencies. Alternatives are claimed to not exist for the vast majority of products from which moulders draw the most value. A 4-years-review period is claimed to be clearly not enough time to substitute MOCA and is seen by the applicant as an overly punitive measure. Still, a-12-years-review period is regarded as being appropriate in order to provide enough time to implement conditions of use and engage in R&D focussed on MOCA replacement whilst the negative economic consequences (due to the non-use scenario) would trend towards zero for the entire supply chain. However, due to the concern expressed by RAC and SEAC in their draft opinion, the applicant suggests a compromise position of a 7-years-review period together with the obligation to submit a progress report on substitution before the authorisation expires, which is regarded as being a more suitable regulatory instrument: it would, in the applicant's view, ensure that moulders are engaging in the replacement of production requiring MOCA and give authorities greater certainty that substitution will continue whilst, at the same time, minimising adverse impacts and not punitively impacting moulders.

- **SEAC's response to the applicant's suggestion to recommend a 7-years-review period as a "compromise position":** The information provided by the applicant in his comments to the draft opinion of RAC and SEAC doesn't include any new information, evidence or argumentation which wasn't already available to RAC and SEAC during the opinion making process. In SEAC's view, the issues highlighted in the applicant's comments to SEAC's draft opinion have already been intensively discussed between the applicant, third parties and RAC and SEAC rapporteurs. The uncertainties surrounding substitution (and respective timeframes for different products affected), as pointed out in the SEAC draft opinion in detail, are still not eliminated and SEAC's recommendation for a 4-years-review period, as reflected in the SEAC draft opinion, is therefore still valid. SEAC again emphasises that the scope of this Application for Authorisation is broad; substitution is currently taking place and will continue in future and it is not clear how much time this will take for all the different products/product parts covered by this Application for Authorisation. This was confirmed by the applicant and 3rd parties. Furthermore, the applicant himself was not clear in his request for a Review Period, which did range from requesting 12 years, to suggesting a staged review period for different products (categorised by weight) and again back to requesting 12 years for the overall scope applied for and finally now the suggestion of a 7-years compromise. Moreover, during the trialogue, the applicant and the moulders participating, indicated that substitution is possible for some of their products already within a 4 year review period. As a consequence, in its assessment of the analysis of alternatives and its recommendation of a short review period, SEAC takes into account the timeframe in which substitution is feasible for some applications covered by the use applied for. In cases where use description has a broad scope and represents a variety of industrial applications, such as the one submitted for MOCA, this review period is expected to give enough time to substitute products wherever feasible. Furthermore, SEAC emphasises that authorisation is not a one-time process, i.e. if an applicant concludes that substitution is not feasible once an authorisation expires, a reapplication for authorisation is always possible. In

conclusion, SEAC did not receive any evidence from the applicant that would result in a change in SEAC's opinion and that would lead to a recommendation of 7 years.

- **SEAC's response to the applicant's proposal to provide a progress report on substitution:** in case the applicant submits a review report, the relevant parts of the initial Application for Authorisation would need to be updated, including the Analysis of Alternatives highlighting the efforts made in this respect. Regarding an additional, so-called "progress report on substitution" by the applicant, to be submitted before the authorisation expires, it is not clear to SEAC what the purpose and the recipients of such a report would be, as it would trigger a new evaluation of the actual situation with regard to substitution (and a possible withdrawal of the granted authorisation for those products where substitution is already feasible), and this is what is foreseen by REACH after the expiry of the review period anyhow.

SEAC's response to the applicant's claim that compliance with the potential occupational limit value (OELV) for MOCA would add to financial pressure and increase business uncertainty: OSH legislation can be considered as complementary to REACH and an applicant might wish to consider and assess potential costs related to compliance with legislation other than REACH in its application for authorisation. In relation to the impact assessment study initiated by the European Commission (mentioned by the applicant) on OELVs (including one for MOCA), given a potential amendment of the OSH legislation, no outcome is available yet, and it is still unclear whether a change of legislation will result. Therefore, the occurrence of any additional investment for complying with potential new OELVs/STELs as indicated by the applicant in his comments on SEAC's draft opinion, is also unclear. Additionally, RAC specified in its response to the applicant's comments that the conditions proposed by RAC may already facilitate compliance with potential new OELVs which, in turn, could lead to cost savings rather than to a cost increase. In conclusion, as the applicant did neither include this type of cost in his cost assessment, nor did he provide any information on its expected magnitude, SEAC has no further information to be used for the recommendation of the review period.

For these reasons, SEAC considers that there is no new information or evidence provided by the applicant in his recent comments that would allow a change in SEAC's opinion.

Annex 1:

Literature references related to the biomonitoring of MOCA in polyurethane manufacturing:

1. Cocker J, Nutley BP, Wilson HK (1996). Methylene bis (2-chloroaniline) MbOCA): towards a biological monitoring guidance value. Biomarkers 1:185-189.
2. Cocker J, Cain JR, Baldwin P, McNally K, Jones K (2009). A survey of occupational exposure to 4,4'-methylene-bis (2-chloroaniline) (MbOCA) in the UK. Ann Occup Hyg 53(5):499-507.
3. Robert A, Ducos P, Francin JM (1999). Biological monitoring of workers exposed to 4,4'-methylene-bis-(2-orthochloroaniline) (MOCA). II. Comparative interest of "free" and "total" MOCA in the urine of exposed workers. Int Arch Occup Environ Health 72(4):229-237.
4. Keen C, Coldwell M, McNally K, Baldwin P, McAlinden J, Cocker J (2012) A follow-up study of occupational exposure to 4,4'-methylene-bis(2-chloroaniline) (MbOCA) and isocyanates in polyurethane manufacturing in the UK. Toxicol Lett 213:3-8.

Annex 2: Comparison of the properties of the assessed alternatives against the properties / key requirements for MOCA (taken from the application for authorisation)

a.) Summary of the outcome of the applicant's assessment of the "like-for-like substitution of MOCA within a TDI System"

Table 13. Summary of the TDI based amine alternatives to MOCA

		Dimethylthiotoluene diamine (DMTDA)	3,5-diamino-4-chloro benzoacid isobutyl ester (1604)	MCDEA
Part Size	**Feasibility**			
Small	**Technical**	Technically possible for some applications. Insufficient technical properties e.g. load bearing and dynamic performance on some finished products.	Cracks in the final product suggest that this alternative is not a suitable alternative for all applications, though it is likely feasible for some.	Cracks in the final product suggest that this alternative is not a suitable alternative for all applications though it is likely feasible for some. Short pot-life means that it is not feasible for even some small products. Insufficient technical properties e.g. load bearing and dynamic performance on some products.
	Economical	More expensive than MOCA. Moulders are unlikely to be able to absorb the increased cost. Products cured with MOCA likely to be imported from outside the EEA.	More expensive than MOCA. Moulders are unlikely to be able to absorb the increased cost. Products cured with MOCA likely to be imported from outside the EEA. Additional costs would also be incurred should there be an increased amount of rejected parts.	More expensive than MOCA. Moulders are unlikely to be able to absorb the increased cost. Products cured with MOCA likely to be imported from outside the EEA. Additional costs would also be incurred should there be an increased amount of rejected parts.
Medium	**Technical**	Technically possible for some applications but depends on shape.	Cracks in the final product suggest that this alternative is not a suitable alternative for all applications.	Cracks in the final product suggest that this alternative is not a suitable alternative for all applications.

		Insufficient technical properties e.g. load bearing and dynamic performance on some finished products. For some moulders hardness and tear resistance not good enough for their products.		Short pot-life means that it is not feasible. Insufficient technical properties e.g. load bearing and dynamic performance on some finished products.
	Economical	More expensive than MOCA. Moulders are unlikely to be able to absorb the increased cost. Products cured with MOCA likely to be imported from outside the EEA.	More expensive than MOCA. Moulders are unlikely to be able to absorb the increased cost. Products cured with MOCA likely to be imported from outside the EEA. Additional costs would also be incurred should there be an increased amount of rejected parts.	More expensive than MOCA. Moulders are unlikely to be able to absorb the increased cost. Products cured with MOCA likely to be imported from outside the EEA. Additional costs would also be incurred should there be an increased amount of rejected parts.
Large	**Technical**	Short pot-life means that it is not feasible in the majority of the applications.	Cracks in the final product suggest that this alternative is not a suitable alternative for all applications.	Cracks in the final product suggest that this alternative is not a suitable alternative for all applications. Short pot-life means that it is not feasible in majority of the applications.
	Economical	More expensive than MOCA. Moulders are unlikely to be able to absorb the increased cost.	More expensive than MOCA. Moulders are unlikely to be able to absorb the increased cost. Additional costs would also be incurred should there be an increased amount of rejected parts.	More expensive than MOCA. Moulders are unlikely to be able to absorb the increased cost. Additional costs would also be incurred should there be an increased amount of rejected parts.
	Availability	This alternative is available in the quantity and quality in specifications that would be suitable for some use.	Unknown. It has been stated in the supply chain that the availability of this alternative is uncertain.	This alternative is available in specifications that would be suitable for use, however, the yield from the MCDEA production reaction relatively low and requires extreme reaction conditions (200 Atms). The ability to upscale at an industrial level any production to a level that covers all current MOCA use is, consequently, uncertain.
	Risk Reduction	This alternative is not considered a carcinogen, mutagen or reprotoxic substance, and therefore there would be an overall risk reduction for workers in using this substance.	No European Harmonised Classification and Labelling exists for this substance. Self-classification suggests it is not considered a CMR, PBT, vPvB or endocrine disrupting substance.	No European Harmonised Classification and Labelling exists for this substance. Self-classification suggests it is not considered a CMR, PBT, vPvB or endocrine disrupting substance. It has been reported by the supply chain however that the production of MCDEA causes high levels of waste (solid, liquid and gaseous). The gaseous wastes can contain aromatic pollutants such as benzene derivatives.
Conclusion		DMTDA is not a feasible alternative to MOCA due to technical reasons for larger parts; and technical and economic reasons for small/medium sized parts.	Cracks in some parts mean that this is not a technically feasible alternative for some products. 1604 is not a viable alternative to MOCA due to economic feasibility. The current reagent cost is too high for SME's to absorb. The availability of it in the required quantity and quality is also a matter of concern.	Given the short pot-life it is not considered a technically feasible alternative. Additionally, MCDEA is not a viable alternative to MOCA due to its cost. The current reagent cost is too high for SME's to absorb. The availability of this alternative in the required quantity is uncertain.

b.) **Summary of the outcome of the applicant's assessment of the use of MDI-based systems:**

Table 16. Summary of the MDI based alternatives to MOCA

		MDI/BDO	MDI/Other
Part Size	**Feasibility**		
Small	**Technical**	Processing issues including voids or bubble formation within the product. Poor shape formation for some products. Provided products with poorer properties, such as tensile strength and hardness. Not a suitable alternative for some applications. Pot-life too short, even for some small products. Problems with products that require high temperature resistance. Suitable for light applications, not suitable for parts requiring long elongation or strong compression. System is not accepted by the vast majority of customers and difficulties in maintaining process stability with equipment owned by the company. Poor quality in the final product.	Processing issues including voids or bubble formation within the product and poor shape development and miscibility issues. Cracks in the final product. Poor shape formation. Provided products with poorer properties, such as tensile strength and hardness. Not a suitable alternative for some applications. Suitable for light applications, not suitable for parts requiring long elongation or strong compression.
	Economical	The MDI/BDO system is a less expensive reagent than MOCA, therefore there are no significant issues surrounding reagent costs.	The cost of the material is comparable to MOCA, however, there has been reported increased quantities of rejected parts and/or the possible need for new machinery/moulds.
		Possible need for new/modified machinery and new moulds. Not suitable for all applications for which MOCA is used.	Not suitable for all applications for which MOCA is used.
Medium	**Technical**	Processing issues including voids or bubble formation within the product. Generally provide products with poorer properties, such as tensile strength and hardness. Therefore not suitable for some applications.	Provided products with poorer properties, such as tensile strength and hardness. Not a suitable alternative for some applications and miscibility issues. Cracks in the final product. Poor shape formation. Suitable for light applications, not suitable for parts requiring long elongation or strong compression.
	Economical	The MDI/BDO system is a less expensive reagent than MOCA, therefore there are no significant issues surrounding reagent costs. Possible need for new/modified machinery and new moulds.	
Large	**Technical**	Processing issues including voids or bubble formation within the product. Processing of large parts difficult/impossible due to the short pot-life for many products. Increased shrinkage compared to MOCA/TDI causes problems for large pieces/coatings. Generally provide products with poorer properties, such as tensile strength and hardness. Therefore not suitable for some applications.	Processing of large parts difficult/impossible due to the short pot-life for many products. Generally provide products with poorer properties, such as tensile strength and hardness. Therefore not suitable for some applications. Difficulties in maintaining process stability.

		Difficulties in maintaining process stability.	
	Economical	The MDI/BDO system is a less expensive reagent than MOCA, therefore there are no significant issues surrounding reagent costs. Problems with processing will lead to poorer products and higher rates of rejection.	
	Availability	This alternative is available in the quantity and quality in specifications that would be suitable for use.	
	Risk Reduction	All isomers of MDI are included in Annex XVII (Restriction) of the REACH regulation.	All isomers of MDI are included in Annex XVII (Restriction) of the REACH regulation.
Conclusion		As mentioned already, most moulders have MDI production capabilities, but are unable to substitute all applications. Though the MDI/BDO system is cheaper than TDI/MOCA it fails to provide equivalent technical properties for some applications. Additionally, the processing is more difficult and the pot life is shorter meaning that this is not a technically feasible alternative.	Most moulders have MDI production capabilities, but are unable to substitute all applications as it fails to provide equivalent technical properties for some applications. Additionally, the processing can be more difficult and the pot life can be shorter meaning that this is not a technically feasible alternative.