

ANALYSIS OF ALTERNATIVES

Addendum

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Submitted by: REACHLaw Ltd.

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Substance: 2,2'-dichloro-4,4'-methylenedianiline (MOCA), EC No.: 202-918-9
CAS No.: 101-14-4

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

Use number: 1

CONTENTS

LIST OF ABBREVIATIONS 3

1. SUMMARY 4

 BACKGROUND TO THE COMMISSION REQUEST..... 4

 OTHER RELEVANT COURT RULINGS POST SUBMISSION OF THIS APPLICATION..... 5

 BACKGROUND TO THE SUZHOU UPSTREAM APPLICATION..... 5

2. UTILIZATIONS WHERE SUITABLE ALTERNATIVES ARE NOT GENERALLY AVAILABLE (NO-SAGA) 6

 2.1 RATIONALE GIVEN FOR NO-SAGA 6

 2.2 SUBSTITUTION ACTIVITIES BY NO-SAGA COMPANIES 8

 2.3 PU PRODUCTS MANUFACTURED WITH TDI/MOCA WHERE THERE ARE NO SUITABLE
 ALTERNATIVES GENERALLY AVAILABLE..... 10

3. SAGA CRITERIA..... 12

REFERENCES..... 14

 Appendix I..... 15

TABLES

Table 1 Examples of the alternative systems reported as tested	9
Table 2 Details from companies that report successful substitution of part of their PU portfolios and the sectors where these parts are supplied to	10

FIGURES

Figure 1 Compiled responses given for why no SAGAs are available for the products made with the TDI/MOCA system	7
Figure 2 Compiled responses for the three main factors reported by the no-SAGA respondents that prevent them from substituting use	8
Figure 3 Number of alternative systems tested	8
Figure 4 The number of companies who reported supply of TDI/MOCA PU parts/components to each sector given in the questionnaire	11
Figure 5 The number of sectors PU parts/components each company reported supplying to.....	11
Figure 6 Summary of the types of PU products supplied by the respondents	12
Figure 7 Volume of MOCA used in 2019 by the respondents.....	15

LIST OF ABBREVIATIONS

AoA	Analysis of Alternatives
BDO	Butane-1,4-diol
CAS	Chemical Abstract Service
EC	European Commission
ECHA	European Chemicals Agency
EU	European Union
HQEE	2,2'-p-phenylenedioxydiethanol
LF	Low-Free
LFMDI	Low-Free MDI
MCDEA	4-[(4-amino-2-chloro-3,5-diethylphenyl)methyl]-3-chloro-2,6-diethylaniline
MDI	4,4'-diphenylmethane diisocyanate
MOCA	2,2'-Dichloro-4,4'-methylenedianiline
NDI	1,5-naphthalene diisocyanate
PU	Polyurethane
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAGA	Suitable alternative generally available
SEA	Socio-Economic Analysis
TDI	Toluene diisocyanate
UK	The United Kingdom

1. SUMMARY

The report documents the rationale given by the companies that responded to a questionnaire launched to collect the information needed to fulfil the request received from the Commission relating to this application. The information collected from twelve companies that stated there is no suitable alternative generally available in the EU for the polyurethane products they manufacture with the TDI/MOCA system. An overview of the products they manufacture and the sectors they are supplied to is also included. All twelve companies reported that they have not yet identified a suitable alternative for their PU products and the reasons given relate to product performance (quality), processing challenges and costs with alternative systems tested.

All report that they are continuing to test alternatives as they become available from systems providers. Six of the twelve companies have already submitted authorisation applications or are preparing applications.

The Substitution Plan report for companies designated as having suitable alternatives generally available in the EU is submitted separately.

As outlined in the Substitution Plan report, the Commission requested the submission of this Substitution Plan report following a ruling by the General Court¹ that changed the interpretation of the requirement relating to alternatives that are considered to be generally available. There have been other rulings^{2,3} relating to the interpretation of the definition of intermediate use as per Art 3(15). We request that the Commission also take this ruling³ into account in its decision on the application. We consider that the use of MOCA as a reactant in the manufacture of polyurethanes fulfils the definition for intermediate use as given in the legal text and as clarified in the rulings by the courts. Consequently, authorisation is not needed for this use.

BACKGROUND TO THE COMMISSION REQUEST

The background to this Commission request is given in the Substitution Plan report.

As outlined in that report, we collected information needed to fulfil the Commission request via surveys. To differentiate between uses of MOCA where suitable alternatives are in general available and those where there are none, we included the question

“For the polyurethane products for which you still use MOCA, please select the preferred alternative for MOCA. Please provide the information ONLY for your most important market sector (highest % in the market sector question)”,

Half responded that there was no alternative generally available for the products where they still use MOCA. The other half either selected an alternative from the picklist available or reported more generally “No suitable alternative available to you but your competitors in the same market sector are using an alternative to MOCA”. For the purpose of fulfilling this request from the Commission according to their requirements, we then differentiated the companies into two groups; one group is designated as having “**suitable alternatives generally available**” (**SAGA**) and the other is designated as not having (**no SAGA**).

¹ Judgment of the General Court (Fifth Chamber) of 7 March 2019, Kingdom of Sweden v European Commission concerning Commission Decision authorising the use of lead sulfochromate yellow and of lead chromate molybdate sulfate red, Case T-837/16 available at <http://curia.europa.eu/juris/liste.jsf?language=en&num=T-837/16>

² Judgment of the General Court (Fifth Chamber, Extended Composition) of 25 September 2015, Polyelectrolyte Producers Group GEIE (PPG) and SNF SAS v European Chemicals Agency (ECHA). Case T-268/10 RENV available at <http://curia.europa.eu/juris/liste.jsf?language=en&num=T-268/10%20RENV>

³ Judgment of the Court (First Chamber) of 25 October 2017, Polyelectrolyte Producers Group GEIE (PPG) and SNF SAS v European Chemicals Agency, Case C-650/15, available at <http://curia.europa.eu/juris/document/document.jsf?text=&docid=195945&pageIndex=0&doclang=EN&mode=Ist&dir=&occ=first&part=1&cid=596449>

We have submitted a Substitution Plan report for companies designated as having SAGAs for their polyurethanes. As per the Commission request, this addendum to the Analysis of Alternatives (AoA) report gives the rationale for those companies who responded that there are no SAGAs for their specific PU products/parts for the specific sectors these are supplied.

Note that while some responders supply products to the same general sectors, due to the broadness of the sectors and the diversity of PU parts/components supplied, some responders may have a SAGA while others will not. This distinction is also coming from customer requirements in the sectors. Another complication is that a given responder may consider there is a SAGA for some products and no SAGA for others in their product portfolio.

Here we would like to highlight that the interpretation of suitable alternatives generally available is likely to be subjective and each company may have understood it differently. We do not challenge the choice taken by the company and document the rationale they have given in their response supplemented by information already available in the public domain.

OTHER RELEVANT COURT RULINGS POST SUBMISSION OF THIS APPLICATION

The Commission request to submit a Substitution Plan for this application is a consequence of a decision taken by the General Court on the lead chromate case (T-837/16)¹. Since we submitted this application on the 11.11.2016, there have also been other rulings by the General court (T-268/10 RENV²) and the Court of Justice (C-650/15 P³) relating to the definition of intermediate use that are relevant in decision making on this application.

In light of these rulings, we consider that **MOCA use in the manufacture of cast polyurethanes is intermediate use as per Article 3(15) of the REACH Regulation.**

The reasoning is given in detail in the Substitution Plan report submitted with this addendum to the AoA. We ask the Commission to also include in its decision on this application whether Suzhou DUs' use is intermediate use and therefore exempt from authorisation.

BACKGROUND TO THE SUZHOU UPSTREAM APPLICATION

An overview of the application submitted and the opinion of the ECHA scientific committees is given in the Substitution Plan report.

OVERVIEW OF THE QUESTIONNAIRE RESPONSES

As outlined in the Substitution Plan report, we received 24 responses and their use accounts for ca. 200 of the 574 tons supplied to the EU28 in 2019. Of these 24, 12 indicated that there are no suitable alternatives in general available (no-SAGA) for their uses of MOCA ("utilizations" using the terminology given in the Commission request). These users are located in five countries. Of these 12, 6 are preparing or have already submitted downstream user applications. The no-SAGA companies account for 120,5 tons of the 574 supplied to the EU 28 in 2019. A breakdown of the tonnage reported is given in Appendix 1. For those users that did not complete the survey, we can only speculate why responses were not received. Only one UK user responded and it may be that the other users in the UK did not respond as they will be under a different regulation at the end of 2020.

The responses received were anonymised and compiled to prepare this report. As was already described in the AoA report, PU parts/components (e.g. roller covers, wheel covers, pads, belts, moulds, polishing wheels, anvil covers) manufactured with the TDI/MOCA system are supplied to end users in diverse sectors ranging from aerospace, automotive, ceramic, paper and pulp, packaging, steel, iron and aluminum industries. Some of the users have portfolios covering 1000's of polyurethane products (referred to as generalist moulders in the application reports) while others have a more limited portfolio and manufacture these in high volumes (referred to as specialist moulders in the application reports). Due to the diversity of the PU products, the AoA-SEA report differentiated between the polyurethanes based on the size of the products manufactured; small, medium and large. The rationale was based on the differing requirements in the manufacture of parts of different sizes; larger parts being more sensitive to the system pot life.

In this addendum, we document their rationale for why they considered there are no SAGAs to the TDI/MOCA system for their PU parts/components and their ongoing substitution efforts to identify a suitable alternative. Details on the types of PUs manufactured are also given based on the questionnaire responses.

2. UTILIZATIONS WHERE SUITABLE ALTERNATIVES ARE NOT GENERALLY AVAILABLE (NO-SAGA)

This application is specific for the use of MOCA in the TDI/MOCA system. As outlined in the AoA submitted, the TDI/MOCA system is very versatile and through variation of polyol used to manufacture the prepolymer, the component ratios and process parameters like heating and cure times, the material properties of the cast polyurethane can be tailored for specific utilizations. Key material properties relating to PU product performance include hardness, tensile strength, heat resistance, cut resistance, tear resistance, compression set, resilience, abrasion resistance, hydrolysis resistance, oil resistance and elongation at break. This means that TDI/MOCA PUs do not refer to one specific PU but rather a very large family of PUs with properties that are tailored to where the product (e.g. wheel covers, roller covers, pads, belts) will be used (e.g. industrial installations in mining, metal processing, energy, paper and packaging sectors, conveyance systems, offshore installations). The TDI/MOCA system is also very versatile and can also be used to manufacture both small and large PU parts due to its long pot life.

As outlined in the Substitution Plan report submitted with this addendum, there are many systems available to manufacture polyurethanes and the choice of system depends on the type of product and the material properties needed for its end use. Cast PU parts/components are very widely used in diverse sectors. As PU material properties can be tailored to specific uses, the specifications for properties depend on where the part is used. As outlined in the substitution plan report, more than 80 % of cast polyurethane moulders in the EU28 use non-MOCA based systems. There are therefore many systems available and whether these systems can be considered suitable alternatives in general to replace the TDI/MOCA system depends on the type of product being made and where this product will be used. Of the 12 respondents, 5 reported that they have already successfully substituted TDI/MOCA for products in their portfolios with suitable alternatives where there were available. Two of these reported that they have already substituted 90 % of their PU portfolio and that their use of TDI/MOCA is solely for utilizations where they have not been able to identify a suitable alternative (5-10 % of the PU portfolio). More details are given in section 2.2 of this report.

The parties who responded that there is no-SAGA available for the manufacture of their polyurethane products are all actively testing alternative systems and to date, they have not identified a system that would be suitable to manufacture their products. As outlined in the AoA, the pot life and technical processing issues for casting large polyurethane products means that larger products (e.g. covers on massive rollers) pose more challenges in terms of identifying suitable alternatives that are technically and economically feasible in the EU. To date, the concerned downstream users have not identified suitable alternatives for these utilizations.

2.1 RATIONALE GIVEN FOR NO-SAGA

For companies that selected “no-SAGA” in the questionnaire, there were additional fields to report their rationale for this statement. They were asked to select from the following four options (1) customer acceptance (2) process limitations (3) product requirements (4) other. The compiled responses are given in **Figure 1**. Seven companies selected reasons (1) to (3). One company selected reasons (1), (2) and (4). One company selected all four reasons. Two of the companies only selected reason (3) “product requirements”. As can be seen from the figure, eleven of the twelve respondents listed **product requirements** as their rationale for why they consider there is no SAGA for their specific PU products.

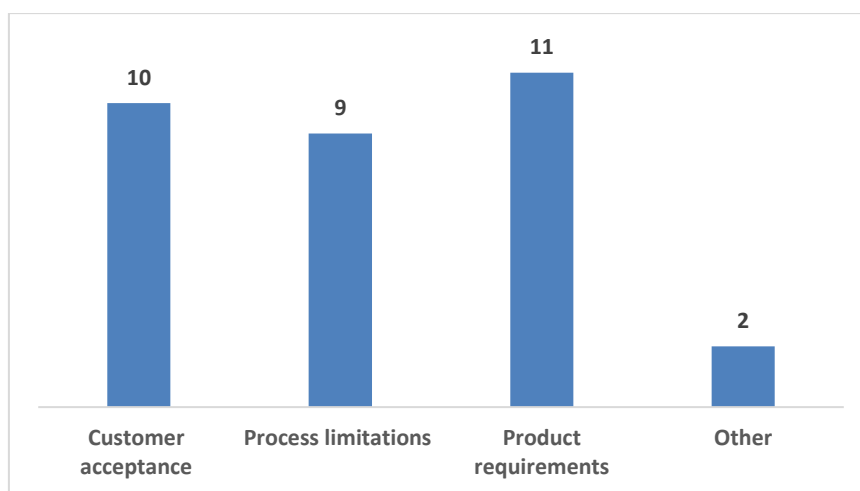


Figure 1 Compiled responses given for why no SAGAs are available for the products made with the TDI/MOCA system

In the free text fields for each option, the respondents included explanations for their selections. Ten of the twelve respondents provided explanations and these are summarised below.

1. Customer acceptance

Many reported that customer acceptance can be technical (quality is not sufficient relating to material properties relating to performance in use, durability, chemical resistance etc.) and economic (cost is not competitive, article service life is shorter).

One company reported that the article service lifetime of the rollers made with alternatives is shorter. Another reported that the anvil covers made with alternatives have a 40 % lower service lifetime. Another reported that their customers take quality, price and processability of the material into account when placing orders.

2. Process limitations

Pot life was the process limitation listed by six of the eight companies that provided answers in the free text field. One company that did not specifically list pot life outlined that the production process has a higher scrap rate as the process is more sensitive to small changes. Another outlined that the curing time and post curing time with alternatives are longer meaning that productivity is lower. Another listed high scrap rate, short shelf life and release agent issues.

3. Product requirements

All reported that the alternatives do not meet the specifications for material properties needed for the end use of the PU component. Specific material properties given included hardness, abrasion resistance, coefficient of friction, plasticity, durability and chemical resistance. Note that all the respondents make PU parts to specification for their customers – the specifications will depend on the sector.

4. Other

Two companies provided answers under “other”. One outlined that the alternative is not economically feasible. The other outlined that despite their testing of alternative systems, they have only managed to identify two alternatives that may be suitable but these are not available on the market.

The questionnaire also had free text fields for all respondents to give the three main factors that prevent them substituting MOCA. Their answers were analysed and grouped according to the reason given. The

compiled answers from the non-SAGA respondents is given in **Figure 2**. Reasons relating to product quality were given by eleven of the twelve respondents and reasons relating to processing by ten of the twelve. Economic reasons were given by nine of the twelve responses.

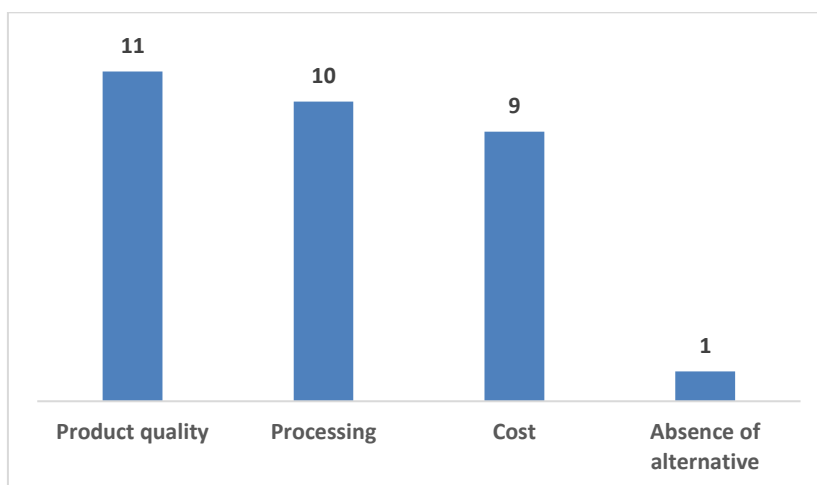


Figure 2 Compiled responses for the three main factors reported by the no-SAGA respondents that prevent them from substituting use

2.2 SUBSTITUTION ACTIVITIES BY NO-SAGA COMPANIES

All the respondents reported R&D activity relating to identifying a suitable alternative to the TDI/MOCA system. Eleven have reported to have conducted tests on alternative systems. The compiled list of the number of alternative systems tested is given in **Figure 3**. For the remaining company, it is more likely that they will stop using MOCA altogether instead of substituting as MOCA-based products only account for 5 % of their annual global turnover.

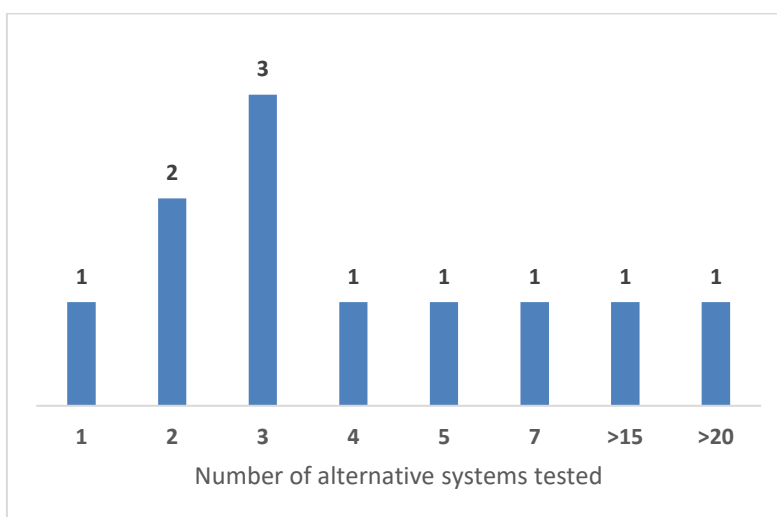


Figure 3 Number of alternative systems tested by the twelve companies

The questionnaire also collected details of their ongoing R&D activities. Their responses are summarised below.

One company reported that they have carried out nine different trials casting with 7 different polyurethane systems that they have developed with four different systems providers before the sunset date. They produced prototypes to be tested internally with a test bench machine including 3 systems tested by end

ADDENDUM TO THE ANALYSIS OF ALTERNATIVES

users. After the sunset date, they report that they have collaborated jointly with 4 alternative providers to develop a system where the PU product has the necessary mechanical properties (high resistance to cutting and abrasion)

Another reported that they have tested many systems and tried to optimise the process parameters but all were unsuccessful. They have also worked with external consultants but without success.

Another reported that before the sunset date they focussed on finding a one-on-one alternative (diamine replacement) for MOCA. They were also testing blending of chain extenders, (LF-)MDI systems and NDI systems. All these systems were tested against the following PU acceptance criteria (in chronological order). If one criterion wasn't met, testing was discontinued.

1. Reproducibility & hardness
2. Mechanical properties
3. Dynamical properties & coefficient of friction

Since the sunset date, they continue testing new systems being placed on the market and have done additional tests with diamine blends. They have not identified a suitable alternative to date.

Another reported that they are working with systems providers to identify suitable alternatives but to date, none of those tested has yielded PU with their product specifications.

Another company reported that they had tested the available amine alternatives without success before the sunset date. After they have set up a workshop with dynamometer and other equipment to be able to test material properties of prototypes. They have currently tested about 200 test pieces made with alternatives to MOCA for compression set, elongation, rebound, cut resistance and other material properties. They reported that they have hired an engineer for the MOCA replacement project.

Another reported that they have trials with alternatives both internally and externally, they have hired new employees and invested in new casting machines.

Not all responders reported the names of alternative systems tested. The alternative systems as listed by the respondent are given in **Table 1**.

Alternatives tested by the respondents
Caprolactones WITH TDI/ MCDEA
TDI / MCDEA
TDI/Ethacure 300
TDI/Addolink 1604
TDI/IMUCURE 107
MDI/HQEE
MDI/BDO
NDI/BDO
LFMDI systems
NDI systems

Table 1 Examples of the alternative systems reported as tested

As outlined earlier, five of the twelve respondents reported that they have successfully substituted the use of the TDI/MOCA system for some of the PU product portfolios. Details of the percentage of their portfolios

ADDENDUM TO THE ANALYSIS OF ALTERNATIVES

already substituted, the alternative system used and the sectors where the products are supplied to are given in **Table 2**.

% PU product portfolio already successfully substituted	Substituted TDI/MOCA with	Sectors where these PUs products manufactured with alternative systems
5-10	MDI / BDO	Wheels for paper cardboard industry Wheels of various kinds for the corrugated cardboard industry
5-10	MDI / BDO	Technical trade Mining Glass Ceramic
90-95	TDI / Ethacure 300	aviation industry automotive industry Printing Machinery Packaging Machinery
25-30	TDI / Ethacure 300 TDI / Addolink 1604 MDI / HQEE MDI / BDO NDI / BDO	Food, healthcare and other industries where possible.
95-100	Polyester quasi MDI/ 1,4BD	All sectors listed in the survey

Table 2 Details from companies that report successful substitution of part of their PU portfolios and the sectors where these parts are supplied to

2.3 PU PRODUCTS MANUFACTURED WITH TDI/MOCA WHERE THERE ARE NO SUITABLE ALTERNATIVES GENERALLY AVAILABLE

The questionnaire collected information on the sectors TDI/MOCA PU products are supplied to. The nine sectors listed in the questionnaire were based on information in the public domain where PU parts/components are widely used. The responses are summarized in **Figure 4**. Respondents could select "other" for sectors not on the list and report sectors in the free field. The responses under "other" were Entertainment (3), Food (2), Healthcare (2), Building, Elevation, Railway, Transport, Wood & Timber, Recycling, Automation, Ecological, Agriculture and Handling. Note that for each sector, companies may supply multiple different products, e.g. for glass and glass edge sector, the products include polishing wheels, rollers, wheels. Likewise the same product type, e.g. a roller may be supplied to several sectors such as ceramics, glass, mining, offshore, paper, steel industries.

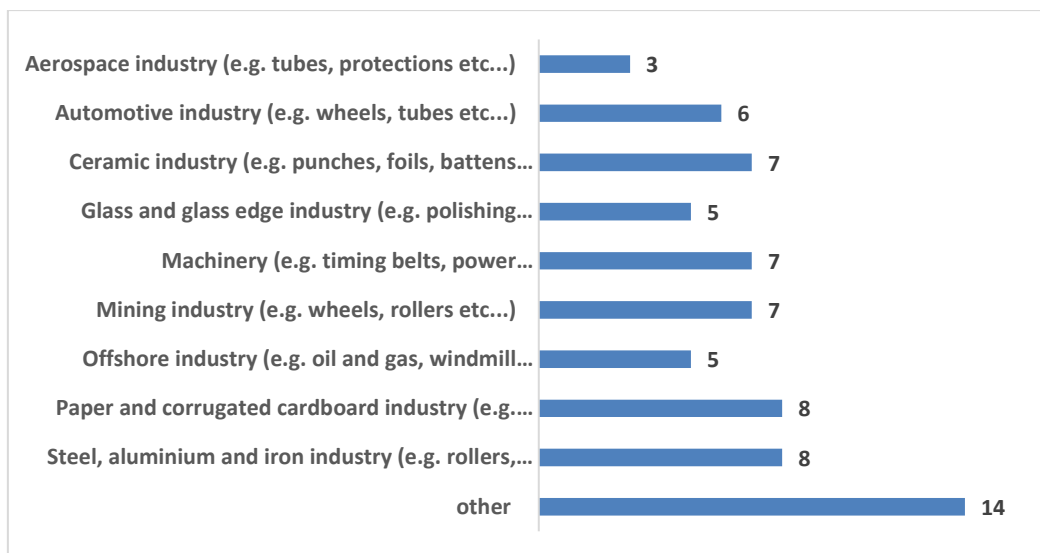


Figure 4 The number of companies who reported supply of TDI/MOCA PU parts/components to each sector given in the questionnaire

Only two companies reported supplying PU parts/components to one sector. At the other extreme, two companies reported supplying to 13 sectors. These would be “specialist” and “generalist” moulders respectively following the terminology used in the application reports. The compiled response from each company is given in **Figure 5**.

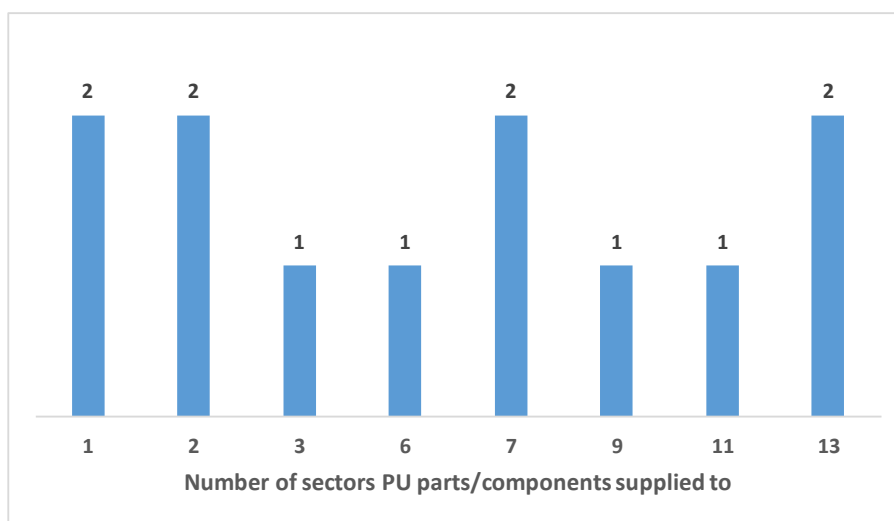


Figure 5 The number of sectors PU parts/components each company reported supplying

The questionnaire also collected information on the PU parts/components manufactured. 9 categories of products were given in the questionnaire and added a category for “other” to enable the respondents to describe in free text fields products that were not covered in our list. The compiled responses supplemented by information from the public domain are given in **Figure 6**. The most reported product type is wheels and rollers. These are in turn supplied to very diverse sectors where they are part of conveyance systems and automation (from rollers moving cables for off-shore pipe laying to rollers moving sheets in steel mills)

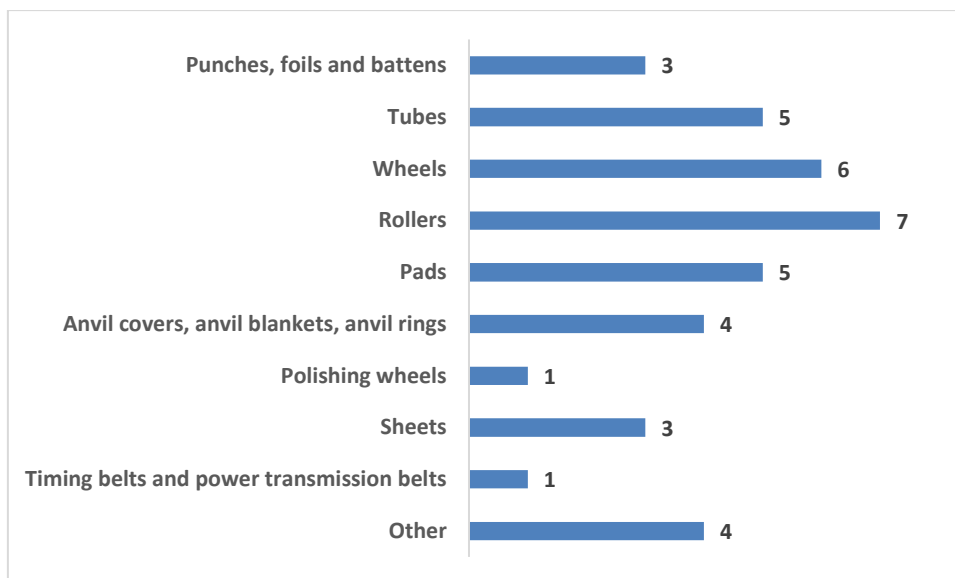


Figure 6 Summary of the types of PU products supplied by the respondents

Figures 5 and 6 illustrate the diversity of PU products that are manufactured with the TDI/MOCA system and also the diversity of sectors they are supplied to.

3. SAGA CRITERIA

As given in the Commission request and further explained in the Commission note to ECHA⁴, users of the Annex XIV substance need to consider whether suitable alternatives are generally available to determine if they need to submit a Substitution Plan. The Substitution Plan needs to document why these suitable alternatives are not technically and/or economically feasible to the users of the Annex XIV substance. The criteria as given in the Commission note⁴ are given below.

Criteria 'suitable alternative'

- *Suitability in the EU, the alternative should:*
 - i. *not be an alternative suitable in abstracto or in laboratory or conditions that are of exceptional nature;*
 - ii. *be technically and economically feasible in the EU; and*
 - iii. *be available, from the perspective of production capacities of alternative substances, or of feasibility of the alternative technology, and in light of the legal and factual requirements for placing them on the market.*

For the companies that reported that there are no suitable alternatives generally available for their utilizations of MOCA in the TDI/MOCA system, all have determined that there are no technically and economically feasible alternatives in the EU for their PU products.

For their utilizations of MOCA that do not have a SAGA, they are not required to submit a Substitution Plan. They will continue their efforts to identify alternatives and will phase out their use of MOCA when suitable alternatives become available from systems providers.

One of the companies highlighted that as they are entirely dependent on the systems providers as their raw material suppliers to develop and commercialise new systems, common interest and collaboration between all actors is needed to successfully phase out the use of the TDI/MOCA system in the EU. As

⁴ Note from the European Commission to ECHA of the 27 May 2020 relating to "Assessment Of Alternatives: Suitable Alternative Available In General&Requirement For A Substitution Plan" available on the ECHA website at https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1

ADDENDUM TO THE ANALYSIS OF ALTERNATIVES

highlighted in the substitution plan report, the continuing use of the TDI/MOCA system by PU moulders based outside the EU means that EU moulders need to remain competitive on price and performance. This distorts the PU market as the Commission cannot regulate the import of TDI/MOCA PU products to the EU under Art. 69(2) based on the MOCA content. Relocation of production sites to outside the EU is probable and/or the market is dominated by cheaper imports.

REFERENCES

Judgment of the General Court (Fifth Chamber, Extended Composition) of 25 September 2015, Polyelectrolyte Producers Group GEIE (PPG) and SNF SAS v European Chemicals Agency (ECHA). Case T-268/10 RENV available at <http://curia.europa.eu/juris/liste.jsf?language=en&num=T-268/10%20RENV>

Judgment of the Court (First Chamber) of 25 October 2017, Polyelectrolyte Producers Group GEIE (PPG) and SNF SAS v European Chemicals Agency, Case C-650/15, available at <http://curia.europa.eu/juris/document/document.jsf?text=&docid=195945&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=596449>

Judgment of the General Court (Fifth Chamber) of 7 March 2019, Kingdom of Sweden v European Commission concerning Commission Decision authorising the use of lead sulfochromate yellow and of lead chromate molybdate sulfate red, Case T-837/16 available at <http://curia.europa.eu/juris/liste.jsf?language=en&num=T-837/16>

Note from the European Commission to ECHA of the 27 May 2020 relating to "Assessment Of Alternatives: Suitable Alternative Available In General&Requirement For A Substitution Plan" available on the ECHA website at https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1

Appendix I

NO-SAGA tonnage

The questionnaire collected information on the tonnage used in 2019. The compiled responses for the companies that reported no SAGA is given in **Figure 7**. The total tonnage reported was 120,5 tons. The median, minimum and maximum values of those reported are 7,5, 1 and 24 tons respectively.

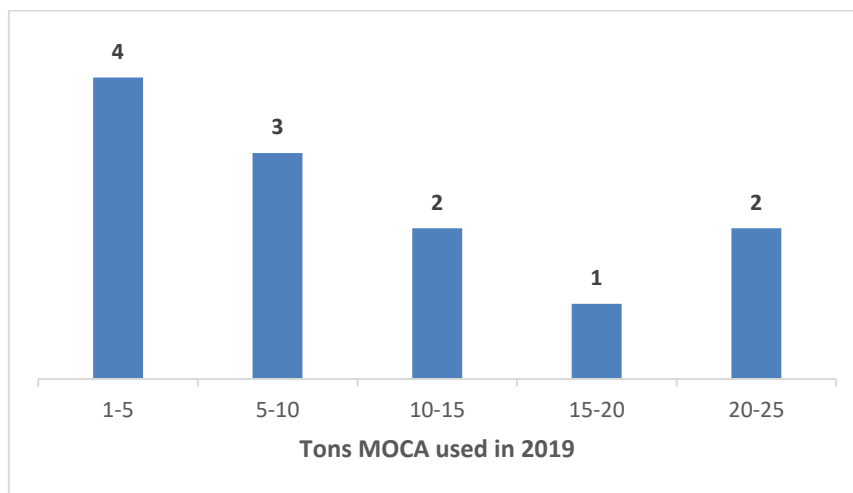


Figure 7 Volume of MOCA used in 2019 by the respondents