29 NOVEMBER 2012

Responses to Comments Document (RCOM) on ECHA's Draft 4th Recommendation for 2,2`-dichloro-4,4`-methylenedianiline (EC number: 202-918-9)

This document provides ECHA's responses to the comments received during the public consultation on the draft 4th recommendation for inclusion of substances in Annex XIV of REACH. In addition to this Response to Comments table, on ECHA's website there is available a zip-file including all attachments to the individual comments (as far as not confidential): http://echa.europa.eu/documents/10162/13640/axiv_rcom_moca_attachments_en.7z

PUBLIC VERSION

CONTENT

I - General comments on the recommendation to include the substance in Annex XIV, including the prioritisation of the substance:

#	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
17	2012/09/19 22:19	ChemSec International NGO Sweden	We support the recommendation to include this substance in Annex XIV.	Thank you for providing your opinion.
16	2012/09/19 21:59 See attachment *16_Trade Union List.xls*	European Environmental Bureau (EEB) International NGO Belgium	The EEB supports the inclusion of this substance in Annex XIV due to its hazardous properties, high production volumes and wide spread uses. It is also a substance that is included in both the SIN List (http://www.sinlist.org/) and the Trade Union Priority List (http://www.etuc.org/a/6023) and cause occupational diseases. The use of this substance in the market is having adverse consequences for public health and environment and should be banned or severely restricted at European level.	Thank you for providing your opinion.
15	2012/09/19 18:42	European Trade Union Confederation Trade union Belgium	ETUC supports the inclusion of this substance in the Authorisation list. This substance is also included in the Trade Union Priority List for Reach authorisation. see: http://www.etuc.org/a/6023	Thank you for providing your opinion.
14	2012/09/19 17:28 See attachment *14_The opinion of CPUIA.doc*	Industry or trade association China		Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **Regarding the classification as carcinogen of MOCA:** 2,2`-dichloro-4,4`-methylenedianiline (EC number: 202-918-9), (MOCA), has been identified as Substance of Very High Concern and included in the Candidate List of substances for eventual inclusion in Annex XIV on 19/12/2011. The identification of the substance is based on its harmonised

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				classification as a carcinogen, Carc. 1B, according to Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008. As the cited harmonised classification is applicable law at present, it will not be questioned or discussed in the context of this recommendation. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification of a substance in Annex VI of Regulation (EC) No 1272/2008 may submit a revision proposal in accordance with the second subparagraph of Article 37(2) of Regulation 1272/2008 to the competent authority in one of the Member States in which the substance is placed on the market. **Regarding low level of risk and availability of alternatives:** Topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a use are important. Information regarding these topics should be provided as part of the application for authorisation (e.g. in the analysis of alternatives, the chemical safety report or the socio-economic analysis). This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. However, it is to be stressed that the prioritisation for the inclusion in Annex XIV is based on the criteria set out in Art 58(3) and follows the agreed approach described in the general approach document (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf). Consequently

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				information on topics such as the availability and suitability of alternatives, socio-economic considerations regarding the benefits of a use or the (adverse) impacts of ceasing a use as well as information on the low level of risk associated to a particular use are not considered in the prioritisation for recommending substances for inclusion Annex XIV.
13	2012/09/19 11:03	MSCA Sweden	We support the prioritisation of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) for inclusion in Annex XIV. The substance has high priority due to high volume and wide dispersive use. In addition, MOCA could be used as replacement for MDA (already in Annex XIV) or technical MDA (prioritised for inclusion in Annex XIV).	Thank you for providing your opinion.
12	2012/09/18 23:32 See attachments *12a_Occup_Med.pdf* *12b_MOCA study.pdf* *12c_MOCA safe use guidance.pdf* *12d_Working safely.pdf*	Polyurethane Manufacturers Association Industry or trade association United States	GENERAL COMMENTS We are submitting the attached comments on behalf of the Polyurethane Manufacturers Association ("PMA"). The purpose of this submittal is to provide the information necessary for ECHA to issue authorization for 4,4 methylene bis (2 chloroaniline) (("MOCA") or "MbOCA"). ECHA refers to MOCA as 2,2' dichloro 4,4' methylenedianiline. Recently, the cancer rating for MOCA was upgraded; however, the true cancer effect on humans from MOCA is still in the early stages of study. Additionally, the health and safety issues for workers from MOCA have been known for decades. Since that time, work practices have been developed for the proper management of MOCA and the health and safety of workers. In conjunction with the regulatory environment, industries have implemented processes involving MOCA use that have substantially reduced worker exposure to MOCA. Thus, the use of measures to protect workers from MOCA exposure have increased dramatically in the past 30 years. When these protective measures are implemented and enforced by employers, worker exposure to MOCA has been demonstrated to be substantially limited. A study of bladder cancer rates from exposure to MOCA is included as Attachment 1; and guideline documents discussing MOCA safe use and handling are included as Attachments 2, 3 and 4. Protective work	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **Regarding the classification as carcinogen:** See response to comment 14 above **Regarding low level of risk and availability of alternatives:** See response to comment 14 above

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			practices such as worker urinalysis, protective clothing and gloves and swipe testing, monitoring and cleaning of work surfaces has been demonstrated to significantly reduce worker exposure to MOCA. At this time, there do not appear to be any suitable alternatives—i.e., an alternative that poses less risk and provides a better product than MOCA. Although MDA might otherwise be considered a suitable alternative to MOCA, MDA is already included in Annex XIV. The attached documents included in the attachments demonstrate that the risk of exposure to MOCA can be substantially reduced when actively managed with a program such as outlined in the PMA MOCA Safe Use Guidelines for the Castable Polyurethane Industry, included as Attachment 3. Thus, PMA respectfully requests ECHA exempt MOCA from authorization. If ECHA decides that MOCA cannot be exempted from authorization, then PMA respectfully requests that MOCA be authorized subject to the protections identified in the attached documents. ATTACHMENT 1 Cancer incidence and Exposure to 4,4'-methylene bis-ortho-chloroaniline (MbOCA); prepared by Abid Dost, J.K. Straughan and Tom Sorahan; June 29, 2009 The study reviews the evidence of a carcinogenic risk from exposure to MbOCA (MOCA) in the United Kingdom. The International Agency for Research on Cancer reclassified MbOCA as a Group 1 carcinogen on the basis of animal (nonhuman) studies. Studies involving humans are noted as providing only "inadequate evidence of carcinogenicity." The study indicated MbOCA exposures were found to have declined significantly over the last 30 years in several companies located in the United Kingdom. The overall conclusion in the paper is that "The findings for bladder cancer should be treated with caution as they relate to a relatively early period of follow up and are based on very small numbers." The Attachment 1 document is included in Section IV of this submittal.	

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			ATTACHMENT 2 MbOCA Handling Practices of PMA Members; prepared by Theodore J. Hogan, Carletta Fowle and Milvis Mamani; August 31, 2009 On August 31, 2009, Dr. Ted Hogan and his research team at Benedictine University released their report of the recently completed PMA study on the MOCA handling practices of PMA members of the castable polyurethane industry. The primary goal of the PMA study was to determine whether voluntary work practice guidelines contained in the PMA's MOCA Use Guidance document resulted in lower workplace exposures to MOCA. The researchers compared PMA member responses to a comprehensive survey regarding MOCA work practices with historical urinalysis data collected by PMA members to see if a link could be established between implementation of the voluntary practices and lower exposures. Although a direct link could not be established between implementation of the guidelines and lower exposures, there were two major findings of the study. First, although the study documented several castable polyurethane facilities that are doing an excellent job following the MOCA Use Guidance document guidelines, it also documented that some of the best practices outlined in the MOCA Use Guidance document are not being consistently followed by all facilities (i.e., ventilation and spill procedures). Second, even though some of the guidelines are not being followed, exposures to MOCA were generally low, with only 3% of monitored employees exceeding the PMA exposure recommendation of 100 ug/L. The PMA study comes on the heels of a study on the exposure to MOCA in the British polyurethane industry, which generally documented housekeeping practices which could be improved but nevertheless found that actual employee exposures were also low. That study also documented tracking of MOCA to areas of facilities where MOCA was not handled, underscoring the need for better handling practices to further reduce employee exposures. The major conclusion of the British study was that British occupational exposure limits should be lowered to act as a stimulus for employers to further reduce exposures to MOCA. It is interesting to note that the 90th percentile of the 2008 PMA member	

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			urinalysis results were approximately 30% lower than the 90th percentile exposures documented in the British study, suggesting that the voluntary practices employed by PMA members yield a better level of protection than the regulatory approach employed in Great Britain. PMA has encouraged urinalysis testing and swipe sample testing of work surfaces for over 35 years. The British and the PMA studies show that actual exposures to MOCA among castable polyurethane processing employees are low, but there are additional opportunities to improve safe work practices to reduce exposures. The Attachment 2 document is included in Section IV of this submittal. ATTACHMENT 3 MOCA Safe Use Guidelines for the Castable Polyurethane Industry; prepared by the PMA, Donald P. Gallo and Theodore J. Hogan; September 2010 Revision This document provides members of the PMA with assistance in developing and implementing appropriate site specific work practices in the use of MOCA (MbOCA) to achieve compliance with applicable health and safety requirements for the castable polyurethane industry. The purpose of this document is to provide guidance to MOCA users regarding the regulatory requirements pertaining to MOCA and procedures that reduce employee exposure to MOCA. Several regulations pertain to MOCA, including those administered by the Occupational Safety & Health Administration ("OSHA"), the U.S. Environmental Protection Agency ("U.S. EPA"), U.S. Department of Transportation ("U.S. DOT") and certain states. For example, OSHA promulgated an air contaminant standard in the 1980s. Although the standard was eventually withdrawn by OSHA in 1993, several states adopted the OSHA standard for MOCA. As a result, control of MOCA particulate contamination has been significantly enhanced with manufacturing changes over time. The guidance recommends several work practices that reduce employee	

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			exposure to MOCA, including: • transferring MOCA pellets from drums to the melting stage • conducting air monitoring in the processing operation • reducing employee exposure to MOCA by skin contact • using respirators (as needed) and ventilating the workplace • using engineering controls, personal protective equipment, work and housekeeping practices to avoid dermal exposure • monitoring MOCA exposures through urinalysis testing • conducting workplace exposure training The last part of the document is an appendix that describes environmental compliance regulations that may pertain to users of MOCA. Several of the regulations have been in effect since the 1970s and 1980s. These regulations include solid and hazardous waste, Emergency Planning and Community Right to Know Act, Clean Air Act, transportation of MOCA and MOCA wastes, Toxic Substance and Control Act provisions, and training to address spilled MOCA. The Attachment 3 document is included in Section IV of this submittal. ATTACHMENT 4 Working Safely with Isocyanates and MOCA (MbOCA) in Polyurethane Casting Shops; prepared by Theodore J. Hogan and Adam Watson; April 1, 2012 This manual explains how to work safely with MOCA and isocyanates in both hand casting and machine casting operations. The primary focus of the manual is to minimize skin exposure to MOCA—the primary way workers are exposed to MOCA and isocyanates. If the provisions included in the manual are adhered to, the health and safety risk that MOCA poses to employees should be considerably reduced.	

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			The manual is prepared in a format both employers and employees can easily read and understand. Discussions in the manual include: • identifying ways employees can be exposed to MOCA both inside and outside the work area • identifying potential short and long term health concerns associated with MOCA and isocyanates • identifying equipment, including gloves, clothing and safety glasses that will protect employees from exposure to MOCA and isocyanates • identifying measures to control exposures and contamination • conducting urinalysis testing to evaluate the overall control measures utilized for MOCA and isocyanates • identifying testing and monitoring measures The Attachment 4 document is included in Section IV of this submittal.	
11	2012/09/18 22:06	Company Belgium	If the substance would be included in Annex XIV and this would lead to restrictions in the usage of the substance, a significant number of polyurethane-elastomers we are manufacturing at the moment could not be manufactured anymore. This concerns mainly technical parts for industrial manufacturing equipment. Since there is no alternative available with which the same set of properties can be achieved business in general could be seriously jeopardized. Since the substance is only present in our facility (closed system) and not in the product we manufacture and supply the solution for a lot of applications could be importing final product from outside the EU, with as result the use of the same substance in the product to create the necessary properties.	Thank you for your comment. **Regarding low level of risk and availability of alternatives:** See response to comment 14 above
10	2012/09/18 22:02	Company Netherlands	If the substance would be included in Annex XIV and this would lead to restrictions in the usage of the substance, a significant number of polyurethane-elastomers we are manufacturing at the moment could not be manufactured anymore. This concerns mainly technical parts for	Thank you for your comment. **Regarding low level of risk and availability of alternatives:**

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			industrial manufacturing equipment. Since there is no alternative available with which the same set of properties can be achieved business in general could be seriously jeopardized. Since the substance is only present in our facility (closed system) and not in the product we manufacture and supply the solution for a lot of applications could be importing final product from outside the EU, with as result the use of the same substance in the product to create the necessary properties.	See response to comment 14 above
9	2012/09/18 21:55	Company United Kingdom	If the substance would be included in Annex XIV and this would lead to restrictions in the usage of the substance, a significant number of polyurethane-elastomers we are manufacturing at the moment could not be manufactured anymore. This concerns mainly technical parts for industrial manufacturing equipment. Since there is no alternative available with which the same set of properties can be achieved business in general could be seriously jeopardized. Since the substance is only present in our facility (closed system) and not in the product we manufacture and supply the solution for a lot of applications could be importing final product from outside the EU, with as result the use of the same substance in the product to create the necessary properties.	Thank you for your comment. **Regarding low level of risk and availability of alternatives:** See response to comment 14 above
8	2012/09/18 21:49	Company Hungary	If the substance would be included in Annex XIV and this would lead to restrictions in the usage of the substance, a significant number of polyurethane-elastomers we are manufacturing at the moment could not be manufactured anymore. This concerns mainly technical parts for industrial manufacturing equipment. Since there is no alternative available with which the same set of properties can be achieved business in general could be seriously jeopardized. Since the substance is only present in our facility (closed system) and not in the product we manufacture and supply the solution for a lot of applications could be importing final product from outside the EU, with as result the use of the same substance in the product to create the necessary properties.	Thank you for your comment. **Regarding low level of risk and availability of alternatives:** See response to comment 14 above
7	2012/09/18 11:09	Individual France	Comment concerning 2.2.2.2 of Draft background document for 2,2'-dichloro-4,4'-methylenedianiline (MOCA) (20 June 2012), 3rd paragraph: Analysis conducted by accredited laboratory show a level of unreacted MOCA in polyurethane articles of 0.025% max., much lower than the REACH SVHCs limit of 0.1% and much lower than the value of 4%	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation.

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			reported by literature cited in ECHA, 2011. See attachment below. Comment concerning 2.2.2.2 of Draft background document for 2,2'-dichloro-4,4'-methylenedianiline (MOCA) (20 June 2012) , 4th paragraph: MOCA has not been used in a "wide dispersive" manner, but only in industry respectively professional settings. The assumed use of MOCA in the form of bi-component resins (resins + hardener) in construction and arts seems to be the result of misinterpretations of information. MOCA is a solid with a high melting point, therefore, it could hardly be used as such. Such applications are completely unknown to us and are also not considered in the registration dossier. Other comments : Results from surface measurements made by a competent authority in France The results from recent analyses conducted by CARSAT show very low levels of MOCA concentrations on surfaces (< 6µg/100 cm²). See attachment. Gloves Boxes Gloves Boxes enable the downstream industry (the producers of the polymers) to use and handle MOCA and MOCA-containing products in a virtually closed environment with no likelihood of exposure. (See for example Gloves Box developed by Baulé). HBM data from Baulé The data in the attached report show that if current safety techniques are applied and pertinent risk management measures are observed, MOCA levels in the urine of MOCA workers are below threshold levels set by Japan and the UK (50 and 35 µg total MOCA per g creatinine respectively, see ANNEX XV – IDENTIFICATION OF 2,2'-DICHLORO-4,4'-METHYLENEDIANILINE (MOCA) AS SVHC.	**Regarding low releases and risk:** ECHA applied the agreed general prioritisation approach to determine which substances should be recommended to be included in Annex XIV. (http://echa.europa.eu/documents/10162/17232/axiv_priority_setting_gen_approach_20100701_en.pdf) Note that the agreed approach is not intended to assess the risks exerted by particular applications of a substance at particular sites of particular actors but to provide a very basic and general assessment of the use pattern and exposure potential a substance may have for humans (workers, consumers) and/or the environment. By doing so a precautionary approach needs to be taken and in particular uses/situations be considered in which risks may potentially not be controlled. Therefore our conclusion that some of the uses appear to have a potential for significant worker exposure in combination with a scoring of 3 is correct although exposure to workers may be controlled in many instances. Also, some uses of the substance have to be considered as wide-dispersive in accordance of the definitions for wide disperiveness given in the document describing general priortisation approach. **Regarding the residue levels of MOCA in polyurethane articles:** We have made clear in the background document and in the prioritisation justification for the substance (http://echa.europa.eu/documents/10162/13640/prioritisation_results_4th_rec_en.pdf) that residual levels can be up to 4% but that normally the level remains below 0.1%, consistent with your data, which however cannot be considered as representative for all uses of the substance or all sites at which it is used. **Regarding professional uses not identified in registrations:**

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				We'll update the background document, expressing clearer that professional uses are not among the uses identified in the registrations. These potential professional uses have been mentioned as a supplementary side aspect in our prioritisation justification but had no impact on the priority rating of the substance.
6	2012/09/18 10:37 See attachment *6_TEGEA.pdf*	Tegea s.r.l. Company Italy	In the experience of a Company that produces MOCA-polyurethane based articles, the market is not yet prepared for the substitution of MOCA from a technical and economical point of view. In our opinion some uncertainties on the relevance for humans of the carcinogenic potential of the substance still exist. On the other hand, workplace exposure monitoring suggests that with proper handling procedures the degree of contamination can be kept at very low levels. Therefore, we suggest as ad interim procedure the establishment of an OEL and related BEI able to warrant the reduction of MOCA exposure to the lowest achievable level with the best available technologies. This proposal is in agreement with the remarks discussed in the Annex XV document, where the concern is related to workers but not to consumer exposure. A more detailed presentation of these comments is available in the attached document.	Thank you for your comment. **Regarding the lack of alternatives:** The Authorisation title, *inter alia*, has the objective (Art. 55) to progressively replace SVHCs by suitable alternatives or technologies where these are economically and technically viable. This does however not mean that a substance cannot be subjected to authorisation before transition to alternative substances or processes has taken place. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance with Art. 62 (4e)). **Regarding low level of risk and availability of alternatives:** See also response to comment 14 above. **Regarding consideration of other risk management Options:** Please note that in the process of assessing whether a substance on the Candidate List has priority for inclusion in Annex XIV and therefore should be recommended for inclusion in this annex we are not in the position to assess

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				alternative regulatory risk management options for the substance or its particular uses. **Regarding the classification of MOCA as carcinogen:** See response to comment 14 above.
5	2012/09/17 23:16	Company United States	The below comments relate to the draft background document for 2,2'-dichloro-4,4'-methylenedianaline (MOCA) published by ECHA on 20 June 2012. Each set of comments will relate to a specific sub section of the background document. Section 2.2.1 comments on volume(s) import / exports. Within the background document it is claimed that the import of MOCA is between 1000-10000t/y, however it is our belief that there is an amount of counting the same volume multiple times within the aggregated registration information. Further comments on this will appear within the confidential section of the comments. Section 2.2.2.2 comments on uses and releases from uses It is commonly accepted that the major exposure route is by dermal exposure. However this can be minimised by the use of correct PPE and adopting good hygiene practices that reduce the risk significantly. A report issued by the UK competent authority (HSE) shows that levels of MOCA in urinary samples has fallen dramatically over the last ten years and that the 90th percentile value of MOCA micromol per mol creatinine is below the biological monitoring guidance value (BMGV) of 15 micromol per mol creatinine. Since 2007, our company has implemented a number of key steps that all our MOCA suppliers are required to undertake in order to minimise the risk of exposure to workers involved in the handling of the MOCA kegs during transportation and storage at our warehouses within the EU. The major one of these is the use of a special barrier inner liner for the MOCA kegs. These inner liners are made from LLDPE/PET. Work carried out by our company has shown that these liners prevent the migration of MOCA through the liner during transport from our suppliers whom are all located in Asia-Pacific region. It is more common for MOCA suppliers to use standard LDPE liners. Our work has shown that MOCA can permeate through these standard LDPE liners and thus be a potential	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **Regarding the allegedly wrong volume:** The estimation of volumes in the scope of authorisation for priority setting relied on data from the registration dossiers as provided in section 3.2 of the IUCLID dossiers. Even though there have been some updates recently, the cumulative volume provided by all registrants is clearly within the range of 1000 t/y – 10 000 t/y. Having the correct volumes reported in the registrations is responsibility of the registrants. ECHA cannot rely on external estimates of the assessment for the volume, as completeness and adequacy of the estimates can not be verified properly. **Regarding low level of risk and availability of alternatives:** See response to comment 14. **Professional uses not covered by registration:** We'll update the background document, expressing clearer that professional uses are not among the uses identified in the registrations. As these potential professional uses only have been mentioned as a supplementary side aspect in our

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			source of dermal exposure when PU processors are handling the MOCA kegs. Also contained within the background document released by ECHA is a statement that un-reacted MOCA may be present in final articles (up to 4%) which could lead to exposure. The article which ECHA have referenced for this claim is a review of ways in which to minimise free monomer content in various polymers produced via a polymerisation process (Polymer Engineering and Science, 2002, Vol 42, pp 1442 – 1468). This review does not mention MOCA at any stage and therefore the figure of 4% should be discounted from the discussion. From an internal review of the chemistry surrounding the curing process using MOCA with various isocyanate systems we can demonstrate that when MOCA is used as a curative under defined and controlled parameters then the amount of un-reacted MOCA is <0.1% in the cured article produced as shown by the table below. The full detail of this will be made available in the confidential section of the webform. Sample # Sample ID Sample Description Total ppm MbOCA in sample 1 LT12137 95% theory, Conventional TDI/ether 60 2 LT12138 100% theory, Conventional TDI/ether 295 3 LT12139 105% theory, Conventional TDI/ether 679 4 LT12140 95% theory, Conventional TDI/ether 26 5 LT12141 100% theory, Conventional TDI/ether 67 6 LT12142 105% theory, Conventional TDI/ether 321 7 LT12143 95% theory, LF TDI/ether 74 8 LT12144 100% theory, LF TDI/ether 369 9 LT12145 105% theory, LF TDI/ether 618 10 LT12146 95% theory, LF TDI/ether 38 11 LT12147 100% theory, LF TDI/ether 58 12 LT12148 105% theory, LF TDI/ether 390 13 LT12149 95% theory, Conventional TDI/ester 27 14 LT12150 100% theory,Conventional TDI/ester 45 15 LT12151 105% theory, Conventional TDI/ester 306 16 LT12152 95% theory, Conventional TDI/ester 30 17 LT12153 100% theory,Conventional TDI/ester 68 18 LT12154 105% theory, Conventional TDI/ester 157 19 LT12155 95% theory, LF TDI/ester 37 20 LT12156 100% theory, LF TDI/ester 59	prioritisation justification this has however no impact on the priority of the substance. **Regarding the residue levels in articles:** We will update the background document to make clear that where adequate technical measures are in place the content of free MOCA in the final article is << 0.1 %. Nevertheless, the data provided by you show that if such measures are not in place, the content of free MOCA rises quickly to amounts in the range of the 0.1 % limit. **Number of "hot cast PU" use sites less than 100:** Information on the supply chain provided in the background document and in particular the approximate number of sites at which the substance is used (more than 200) is based on the Annex XV report and has been obtained by consultation of manufacturers and other actors in the supply chain. We have however no information on the number of sites at which a specific use of the substance is carried out. **Prioritisation scoring:** See our comments on the allegedly wrong volumes and the number of sites above. In addition, we have indication of several activities from the use descriptions in the registrations, in particular for the uses as curing agent in the manufacture of polyurethane, with a significant potential for exposure of workers to the substance. Hence we consider the assigned total score of 17 correct. **Request to exempt hot cast PU processing from authorisation:** If not generically exempted in the REACH Regulation, uses of a substance subject to authorisation can only be exempted from the authorisation requirement on the basis of Article

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			21 LT12157 105% theory, LF TDI/ester 470 22 LT12158 95% theory, LF TDI/ester 33 23 LT12159 100% theory, LF TDI/ester 87 24 LT12160 105% theory, LF TDI/ester 484 Limit of quantification (LOQ) = 20 ppm, all controls were in statistical control In above table Conventional denotes free isocyanate level in prepolymer can exceed 0.1% by weight. LF denotes free isocyanate level in prepolymer is less than 0.1% by weight. As the lead registrant for MOCA in 2010, our dossier contained no Professional Uses. Therefore if various competent authorities are aware of this use then we believe that a review of the supply chain should be performed by that authority / authorities to ensure that this material is only used within industrial settings where the controls and risk management measures (described above and within the lead dossier) can be implemented. By adopting this measure the potential releases would be further reduced and the use would be limited to a smaller number of sites. Section 2.2.2.3 Comments of geographical distribution We do not believe that there are more than 100 downstream hot cast PU use sites of MOCA within the EU. Further information is provided in confidential section to support this comment. Certainly the use of MOCA is for industrial applications only (in the production of hot cast polyurethane elastomers). In this setting MOCA is processed in a controlled environment and the risk for exposure can be minimised by the means discussed above. Within the United Kingdom the HSE has been very active in monitoring exposure to MOCA by workers in industrial settings. Their reports show (as discussed above) that the levels of MOCA found in urine samples has dropped over the last ten	58(2) of REACH. In accordance with this Article it is possible to exempt from the authorisation requirement uses or categories of uses 'provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled'. ECHA considers the following elements when deciding whether to include an exemption of a use of a substance in its recommendation: - There is existing EU legislation addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definitions in accordance with Art. 3(24). Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed; - This EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to e.g. by referring to the classification criteria or the Annex XIII criteria; - This EU legislation imposes minimum requirements[1] for the control of risks of the use. Legislation setting

[1] Legislation imposing minimum requirements means that:
- The Member States may establish more stringent but not less stringent requirements when implementing the specific Community legislation in question.
- The piece of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as proper.

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			years i.e. that the PPE and associated risk management measures are indeed lowering the exposure of workers in industrial settings to MOCA. Section 2.3. Comments on alternatives There is no dispute that there are alternatives to MOCA but none of these can be deemed "drop-in" replacements in fact different curatives result in the final properties of the cast PU articles being different and may mean that the PU article produced is not fit for its intended purpose. Furthermore different curatives have different reactivities, this in turn can result in urethane systems that have very short pot-lives. This would mean that processors would need to possibly invest in new capital equipment in order to produce the parts they are producing today. It may lead to more rejects, off-grade and thus increased scrap rates and potential environmental release of other un-reacted curing agents. The cost of all known alternatives are currently higher than MOCA today by a factor of at least 2x, in some cases >4 x. Since MOCA is produced outside of the EU then cast PU processors who are located outside of the EU will continue to use MOCA and most likely they will handle MOCA with less considerations of the health risks of MOCA than EU processors currently do. The likelihood is that if MOCA is not granted an exemption for use in hot cast PU processing then increasingly the EU processors will close and shift production outside of the EU or they will lose business completely to non EU manufacturers. An example is in the off-shore oil industry where MOCA cured TDI isocyanate / ether prepolymers have been used for over 20 years to fabricate critical parts such as dynamic bend stiffeners. Due to the criticality of the application the user is not going to readily accept a part made from different chemistry without substantial data generation on the new systems. This could take several years to generate and even then there is no guarantee that an alternative curative will work or ensure the same level of safety / control. Substantial efforts have been put in place to handle MOCA safely in the hot cast PU industry and this is why the use of MOCA in this area should be exempted from authorisation. The alternative curatives do not have such an extensive history or body of test data to determine whether they will be "safer" than MOCA in the long term. The risks of MOCA are well known and communicated widely in the industry. With the correct	only the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s) as relevant) are covered by the legislation. On the basis of the criteria above, we made the following observations on the argumentation brought forward by the commenting party: (i) Only existing EU legislation is relevant in the context to be assessed (no national legislation). (ii) Minimum requirements for controlling risks to human health or (and) the environment need to be imposed in a way that they cover the life cycle stages that are exerting the risks resulting from the uses in question. (iii) There need to be binding and enforceable minimum requirements in place for the substance(s) used. This means that solely national legislation or industry's voluntary actions in reducing releases cannot be considered as such as a reason to propose an exemption. From ECHA's assessment of the available information there seems to be no basis for proposing an exemption from authorisation for the use of the substance in hot cast PU processing. **Regarding regulatory effectiveness considerations:** Grouping of chemically and in terms of their hazard potential similar substances is an important strategy to prevent

#	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
			precautionary measures the risks from MOCA have been and can be further reduced within the industrial setting. Section 2.4 Comments on existing specific community legislation. Whilst we are not aware of any specific legislation relevant for possible exemption at the present time, we do believe that the use of MOCA in industrial settings where adequate controls are in place for both the curing time, temperature and the stoichiometry of the pre-polymer / curative system should minimise exposure and therefore almost be the same as intermediates (which are obviously outside the scope of authorisation). Section 3.1 Comments on prioritisation Based on the above detail, then it is our belief that the scoring approach used by ECHA for prioritising 2,2'-dichloro-4,4'methylenedianiline is incorrect. We do not disagree with the Inherent properties score (based on the material being a cat 1B Carcinogen, in agreement with the details laid out in Article 57(a) of the REACH legislation) but we do not agree with the other values that have been assigned during the prioritisation. The volume figure is incorrect as we believe the volume actually imported / used within Europe is <1000t/y therefore the volume score would become 5 from the present 7; the use would be in a non-diffuse / controlled manner therefore the release score would become 1 and with the number of use sites being less than 100 this should be scored as 2. This gives a revised prioritisation value of 8 versus the current proposed 17. As such (based on the general approach for prioritisation of substances of very high concern for inclusion in the list of substances subject to authorisation published by ECHA in May 2010) we believe that the material does not fulfil the priority criteria (a substance with PBT or vPvB properties, or wide dispersive uses or high volumes). In section 2.3 the footnote states that information on alternatives was not used in prioritisation however in section 3.1 ECHA uses the argument that regulatory effectiveness considerations support the recommendation of MOCA. This seems contradictory guidance. Theoretically MOCA could be considered as an alternative to MDA or technical MDA but so could many other curatives. In reality neither are drop-in replacements for the other. MOCA was registered for use as a curative in hot cast PU processes and not for the downstream uses that	evasion of the authorisation requirement *(by replacing one CMR curing agent on Annex XIV by another one not on this Annex)*. Therefore, a precautionary approach is necessary to prevent loopholes. MOCA, MDA and technical MDA are all curing agents with similar structures and technical properties. Grouping is used if it appears in technical terms possible that a particular substance can replace one or more other substances in at least one of their uses.

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			most likely technical MDA was registered for. Conclusions Therefore in conclusion we strongly urge that ECHA / the European Commission considers an exemption for use of MOCA in hot cast PU processing based on the information put forward in this section and the confidential section	
4	2012/09/17 18:19 See attachments *4a_Courbis_Comments.pdf* *4b_Annex 1.pdf* *4c_Annex 2.pdf*	Groupe Courbis Company France	Priority score is based on false or incomplete information, especially if a difference is made between foam polyurethanes and technical dense polyurethanes. We so argue some modifications which should be brought in ECHA's recommendation. Discussion is too complex to be made in this form: Please find attached our comments and requests in document "2012-09-17_COURBIS_Comments-MOCA.pdf" and its two appendices ANNEXE1.pdf and ANNEXE2.pdf. All these documents should be disclosed to the public to offer a full view of our comments. Thanking you.	Thank you for your comment and the additional information provided. This will be taken into account, where relevant, for finalisation of ECHA's recommendation of substances to be included in Annex XIV and the corresponding background documentation. **Regarding low level of risk and availability of alternatives:** See response to comment 14 above. **Regarding the allegedly wrong volume:** See response to comment 5 above. **Number of use sites less than 100:** See response to comment 5 above. **Regarding lower prioritisation for technical dense polyurethanes: :** Please note that the prioritisation is per substance and not per individual use of a substance. The approach, which was agreed by the Member State Committee and applied here to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV is not intended to assess the risks exerted by particular applications of a substance at particular

#	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
				sites (in particular Member States) but to provide a very basic and general assessment of the use pattern and exposure potential a substance may have for humans (workers, consumers) or/and the environment. By doing so a conservative approach needs to be taken considering in particular uses or situations in which risks may potentially not be controlled. Therefore, ECHA's conclusion that some of the uses appear to have a potential for significant worker exposure and therefore – in combination with other criteria – qualify for prioritisation and inclusion in Annex XIV was drawn although risks might be adequately controlled in many instances. **Prioritisation scoring:** See response to comment 5 above. **Regarding the residue levels in articles:** See response to comment 5 above. **Regarding the request to establish upfront review periods:** See response to comment 4 in section IV.
3	2012/09/17 12:03	MSCA Germany	The German CA supports this proposal for inclusion of 2,2'-dichloro-4,4'-methylenedianiline into Annex XIV. The classification as Carcinogenic 1B, may cause cancer, and its use as a curing agent for PU-foams with residual content of up to 4% (ECHA, 2011) while being mainly absorbed via dermal contact, make an exposure of consumers likely. Furthermore being used in bi-component resins for use in construction and arts, a consumer exposure cannot be ruled out.	Thank you for providing your opinion.

#	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
2	2012/09/14 07:07 See attachments *2a_Comments on MOCA.pdf* *2b_Toxicity test.pdf*	Suzhou Xiangyuan Special Fine Chemical Co., Ltd. Company China	Comments on MOCA, 3 pages Toxicity Test Report on MOCA, 11 pages	**Regarding the classification as carcinogen:** See response to comment 14. **Regarding low level of risk and availability of alternatives:** See response to comment 14.
1	2012/09/12 15:19	MSCA Norway	The Norwegian CA supports the prioritization of 2,2`-dichloro-4,4`-methylenedianiline (MOCA) for inclusion in Annex XIV.	Thank you for providing your opinion.

II - Transitional arrangements. Comments on the proposed dates:

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
16	2012/09/19 21:59	European Environmental Bureau (EEB) International NGO Belgium	As soon as possible	Thank you for your comment **Regarding your comment to set the dates related to the transitional arrangements as soon as possible:** ECHA made its proposals for the latest application dates on the basis of discussions by the stakeholder expert group that was following the development of the Guidance for including substances in Annex XIV. This expert group estimated that the time needed for preparation of an authorisation application of sufficient quality might in standard cases require 18 months (roughly 12 months worktime for drafting the application plus an additional buffer of 6 months for consulting required external expertise). As there is yet no reliable information available that would suggest shortening or prolonging this time interval, we consider that a period of 18 months should normally be given to allow for the preparation of a well documented application for authorisation. The anticipated workload of the Agency with regard to processing of authorisation applications was accounted for by grouping the proposed substances in 3 groups and spreading the application and sunset dates over a period of six months. Please note that the REACH Committee agreed in its meeting of 21/22 November 2012 that the latest application dates for the chromium(VI) substances included in the 3rd Recommendation should be set to 35 months after EiF of the inclusion of these substances into Annex XIV (anticipated to be in March 2013). In order to allow consistency amongst all chromium(VI) substances recommended for inclusion in the Authorisation List, the latest application dates for the chromium(VI) substances of the 4th Recommendation are therefore set to 24 months after EiF of their inclusion in Annex XIV (anticipated to be in February 2014). The latest application date for all chromium(VI) substances of the 3rd and 4th Recommendation will then consistently be February 2016. This adjustment of the LAD for the chromium(VI) substances requires a re-organisation of the LADs of the other substances of the 4th

				Recommendation in order to account for an appropriate distribution of the workload in the time provided for. Therefore, it is suggested to change the LADs for MOCA to 21 months after EiF.
2	2012/09/14 07:07	Suzhou Xiangyuan Special Fine Chemical Co., Ltd. Company China	we suggest not to include MOCA in the list.	Thank you for providing your opinion. See also response to comment 2 in section I

III - Comments on uses that should be exempted from authorisation, including reasons for that:

#	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
17	2012/09/19 22:19	ChemSec International NGO Sweden	Being such a hazardous substance, no use should be granted a generic exemption from authorisation.	Thank you for providing your opinion.
12	2012/09/18 23:32	Polyurethane Manufacturers Association Industry or trade association United States	MOCA has widespread uses in several processes and categories. As noted previously, MOCA has been the subject of regulatory consideration for decades. Additionally, measures for reducing employee exposure to MOCA have been developed and implemented by users. Thus, we respectfully request MOCA be exempted from the authorization requirement. If not, we request ECHA grant MOCA with an authorization consistent with the PMA—MOCA Safe Use Guidelines for the Castable Polyurethane Industry (Attachment 3) and related guidelines.	Thank you for your comment Based on the available information on hazard profile, volume used in the EU in the scope of authorisation and the widespread uses with potential for significant exposure the substance has gained high priority for inclusion in Annex XIV. If not generically exempted in the REACH Regulation, uses of a substance subject to authorisation can only be exempted from the authorisation requirement on the basis of Article 58(2) of REACH. In accordance with this Article it is possible to exempt from the authorisation requirement uses or categories of uses 'provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled'. (For further details on exemption of a use on the basis of Article 58(2) please refer to the response to comment 5, section "Request to exempt hot cast PU processing from authorisation"). From ECHA's assessment of the available information there seems to be no basis for proposing an exemption from authorisation for the use of the substance in the Castable Polyurethane Industry.

#	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
7	2012/09/18 11:09	Individual France	Exempted use proposal: MOCA in the production of so-called pre-polymers and polymers. MOCA acts as a monomer (within the meaning of the REACH definition) in the reaction with a diisocyanate to form repeating urea groups in a polymer. This reaction leads to polyurea chains were MOCA becomes a covalently bound monomer unit in the polymer matrix. During this chemical reaction, MOCA is completely consumed and transformed into another substance, the polymer. Owing to the fact that a surplus of isocyanates/NCO-groups is typically used in the production process (without any of the two NH2 function reacted); therefore, the final polymer doesn't contain any significant traces of MOCA (see attached analysis data). MOCA is a monomer and acts as an intermediate in the production of so-called pre-polymers and polymers. For this reason, both applications are exempt from Authorisation.	Thank you for your comment **Intermediate status of the substance:** One obligation arising from inclusion of a substance in Annex XIV is the responsibility of actors to assess whether their uses of the substance are in the scope of authorisation (e.g. whether the use fulfils the definition of an intermediate as set out in Art. 3(15) of REACH[2]) and to keep all relevant documentation supporting their respective conclusion. This information may be requested by any competent authority of the Member State in which the actor is established or by the Agency. Non compliance with the requirements of REACH may result in enforcement actions by the competent authority of the Member State in which the actor is established.
5	2012/09/17 23:16	Company United States	Section 2.4 Comments on existing specific community legislation. Whilst we are not aware of any specific legislation relevant for possible exemption at the present time, we do believe that the use of MOCA in industrial settings where adequate controls are in place for both the curing time, temperature and the stoichiometry of the pre-polymer / curative system should minimise exposure and therefore almost be the same as intermediates (which are obviously outside the scope of authorisation).	See response to comment 5 in section I
4	2012/09/17 18:19	Groupe Courbis Company France	Please see our arguments concerning the score of priority allocated by ECHA. If the criteria are adapted to the specificities of technical dense polyurethanes, this score should be largely dropped (from 17 to 8). Discussion is too complex to be made in this form: Please find attached our comments and requests in document "2012-09-17_COURBIS_Comments-MOCA.pdf" and its two appendices ANNEXE1.pdf and ANNEXE2.pdf. All these documents should be disclosed to the public to offer a full view of our comments. Thanking you.	See response to comment 4 in section I

[2] See the definition of intermediates as defined in Art. 3(15) of REACH and further elaborated in the 'Definition of Intermediates as agreed by Commission, Member States and ECHA: Appendix 4 to the Guidance on Intermediates, version 2, December 2010: http://www.echa.europa.eu/documents/10162/17224/intermediates_en.pdf.

IV - Comments on uses for which review periods should be included in Annex XIV, including reasons for that:

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
12	2012/09/18 23:32	Polyurethane Manufacturers Association Industry or trade association United States	The PMA respectfully requests that ECHA grant an exemption to authorization or grant authorization for MOCA.	Thank you for your comment **See response to comment 12 in section III**
4	2012/09/17 18:19	Groupe Courbis Company France	Based notably on the lower priority score we ask for an application of ECHA's & REACH rules for priority and so to decide an exemption for technical dense polyurethanes. And if competent authorities wish nevertheless to keep a high priority conclusion, we request at least a 6-year review period for hard technical dense polyurethanes and 12-year review period for flexible technical dense polyurethanes. We hope that ECHA will also add a sentence in its recommendation to let the possibility to consider on case by case some specific applications. Discussion is too complex to be made in this form: Please find attached our comments and requests in document "2012-09-17_COURBIS_Comments-MOCA.pdf" and its two appendices ANNEXE1.pdf and ANNEXE2.pdf. All these documents should be disclosed to the public to offer a full view of our comments. Thanking you.	Thank you for your comment **Regarding your request for setting upfront long review periods:** Please note that setting 'upfront' review periods[3] for any uses requires that the Agency has access to adequate information on different aspects relevant for a decision on the review period. ECHA currently assessed that the information available is not sufficient to conclude upfront on specific review periods. Therefore, ECHA has not proposed such review periods. It is to be stressed that all authorisation decisions will include specific review periods which will be based on concrete case specific information provided in the applications for authorisation. With regard to the prioritisation scoring by ECHA and the preconditions for exempting uses of a substance from authorisation please refer to the responses to your comment in Section I (#4), "Prioritisation scoring" and "Request to exempt hot cast PU processing from authorisation".

[3] i.e. review periods already included as entry in Annex XIV and not decided upon, case by case, on the basis of information becoming available in the authorisation application phase of the process.