Comments on ECHA's proposition of 12th June 2012 for 2,2'-dichloro-4,4'-methylenedianiline (MOCA, CAS 101-14-4, EC 202-918-9) inclusion in annex XIV of REACh (public consultation from 20/06/2012 to 19/09/2012).

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SUMMARY:

Our company does not carry out insulating polyurethane foams (e.g. for refrigerators) or rubber bands (e.g. for mattresses), but technical denser polyurethanes only intended for industry. These technical polyurethanes are produced and immediately moulded to form parts which will be integrated in mechanical whole of the aircraft industry, automobile and various other sectors. Thus we have a catalogue of approximately 60,000 elements. A great majority of them have very demanding specifications, even a complete qualification adapted to one or some precise applications. We produce thus on average 20,000 types of element each year with for each one volumes varying from a few units to several thousands. (See appendix-1: a not comprehensive list of elements that we can adapt to industry needs).

It should be noted that two main reasons push our group to formulate comments on this proposition for inclusion in annex XIV: Firstly, MOCA is used for the dense polyurethane synthesis, but is absent in our final products (<0.1% w/w). Secondly, we are highly dependent on MOCA (see table-1 hereafter) and alternatives (as MDA) are already or could also be included in annex XIV or their toxicological and technical profile is unknown or/and not feasible technically and economically.

We would therefore wish that ECHA takes into account the characteristics of our technical dense polyurethanes, initially by clearly differentiating them from polyurethanes foams and so lowering their priority score, and then by differentiating among these dense polyurethanes those harder from those more flexible. This request rests on the fact that concentrations, potentials of emissions and difficulties in substituting MOCA in the processes are not at all equivalent among these various polyurethanes.

Table-1: Groupe COURBIS is composed of 7 companies which highly depend on MOCA:

Companies of Groupe COURBIS	**Dependence on MOCA (%)**	**Sales turnover (Million €)**	**Employees**
Courbis Synthèse	100	17	70
Courbis Industries	70	5	50
Courbis Technologies	70	1	10
Courbis Composites	70	3	20
Courbis Silicones	70	2	10
Courbis Plastiques	30	3	20
Courbis Mastershock	30	5	30
Total	**/**	**36**	**210**
Dependence (%)	**/**	**75**	**70**

ARGUMENTS

Argument-1: The MOCA does not exist any more as an isolated entity in dense polyurethanes, the end product being an elastomer containing less than 0.1% of free MOCA.

The MOCA combined with a pre-polymer with average temperature (100°C) in a closed system ("PROC1: Use in closed process, No likelihood of exposure") is a lengthener of the polymeric chains and joins moreover these chains in a covalent way to form a reticulated network. The result is dense polyurethanes in which the MOCA - which is never in excess in the reaction - is part of polymer and brings the more or less important elastomer's properties. Integration in the form of strong connexions in the matrix is confirmed by the rates of measurable MOCA in the parts which are always lower than 0.1% (see appendix-2: result of analysis in two typical elements produced by our group). These elements are only used within industrial settings and as part of more complex products. So please note that the statement that un-reacted MOCA may be present in final articles up to 4% is fully wrong in the case of our technical dense polyurethanes.

Elsewhere, imports of MOCA are in all probability not between 1 000-10 000 tons per year but much lower: this error can maybe be explained by multiple counts of the same volume within aggregated registration information. In addition there are very probably less than 100 downstream users' sites within the EU.

Argument-2: The properties of technical dense polyurethanes are different and thus the potential exposures cannot be considered in the same manner as for foam polyurethanes. For technical dense polyurethanes, exposures cannot be considered as "dispersive".

The production of approximately 600 tons of dense polyurethanes implies on average the use of approximately 60 tons of MOCA a year. In our group, the conditions of storage in form of coated granules and in sealed barrels, and the direct transfer in closed system towards the systems for the reaction and the moulding cannot be regarded as with potential of "dispersive" exposures. Furthermore, major exposure route is by dermal route so that it can be easily minimised by PPE and good hygiene practices. The UK competent authority (HSE) shows that between 1996 and 2008 the 90th percentile of urinary MbOCA data from HSL's biological monitoring database has remained around the range of 5 to 10 µmol/mol creatinine, against a UK biological monitoring guidance value (BMGV) of 15 µmol/mol creatinine, and that there was scope for improvements in exposure controls (Research Report RR828, Health and Safety Executive, 2010).

Moreover, at the time of the manufacturing processes, the proportion of MOCA is between 6 and 20% (w/w) to adjust to a function requiring rather elasticity or hardness, respectively. These elements will have a very long lifetime without any degradation of the elastomeric properties because the MOCA remains in its form integrated into the matrix

Elsewhere, as regards the uses for which are intended the harder polyurethane elements, abrasion could possibly generate some exposures; this however cannot be considered the case of flexible polyurethanes which are used for functions of damping without any condition of abrasion.

Argument-3: The possibilities of substitution of polyurethanes are very variable among our products. Our R&D and socio-economical works show thus certain possibilities provided that a sufficient time is allocated with the change of process, but also certain technical and economical impossibilities.

Substitutions by other amines is not easy, firstly because the hazard and exposure profiles of these substituents are not clearly guaranteed, and secondly because they are associated with great technical and economical difficulties.

Theoretically, MOCA could be considered as an alternative to MDA. In reality, no drop-in replacements exist. There still, a clear difference can be made between hard polyurethanes for which, with variable difficulties, substitution could be under consideration with more or less long run, and flexible polyurethanes for which the difficulties can quite simply mean impossibility for our company to survive a prohibition.

At least 50% of our applications present difficulties to substitution, not only technically because the particular properties of the MOCA are unique, but also because of many organisational reasons. In addition, all parts of our group are impacted so that it cannot be planned to change or delete only one part of the group.

Among these 50%, for 2/3 a substitution could be possible, but would be associated with more or less technical and economical difficulties. For example: how to make functioning in parallel our 20 machines able to work on bi-components mixtures with new machines (to be acquired) able to work on tri-components mixtures? Should we lose the important investment we made in the bi-components machines? Can we stop the production during the time to develop the new formulations on new machines?

Among these 50%, for the remaining 1/3, a substitution will not be possible considering the particular properties brought by MOCA and the specifications requested by the clients: Elements used in applications for which plans are reviewed for 10 to 30 years, as the rotors of blades of helicopter, shock absorber inside a wheel, elastic component in the structures of a bridge. These productions are thus impossible to substitute in a sufficiently fast way for our customers who will quite simply recover these parts or will manufacture the whole out of Europe. Re-qualifications of our products for such industries are complex, need time and are expensive.

REQUESTS

The priorities worked out by ECHA in its draft recommendation are maybe adapted to polyurethane foams, but not to technical dense polyurethanes. We thus request ECHA to adapt by splitting its opinion in two parts to take into account the fundamental differences between these two industries.

We so ask to ECHA to modify its recommendation in order to

- **distinguish the two subcategories: On the one hand polyurethane foams, and on the other hand technical dense polyurethanes,**

- **and to attribute to the latter (technical dense polyurethanes) a much lower priority score (see next paragraph) using the arguments describes in this document.**

If REACH's rules are respected,

- **this should result in the recognition that MOCA used in technical dense polyurethanes cannot be considered as a priority anymore compared to other candidate substances to annex XIV**

- **and/or that an exemption of technical dense polyurethanes from REACh Authorisation should be decided.**

If the authorities wish nevertheless to keep a priority conclusion on technical dense polyurethanes, we strongly ask that the characteristics of our industry are taken into account (notably: much less potential exposures, strong technical and economical difficulties to substitute). As a result, we believe

- **the scores "Volume" and "Wide Dispersiveness & Uses" are not appropriated and should be modified for technical dense polyurethanes. This would then lower the "V" score from 7 to 5 and the "WDU" score from 9 to 2, and so the total priority score for technical dense polyurethanes from 17 to 8.**

  - **The "volume" score should be 5 instead of 7, because produced amount is less than 1 000 tpa;**
  - **the "release" score should be 1 instead of 3 in the case of technical dense polyurethanes because of the almost inexistence of MOCA in these polyurethanes and the very low possible releases;**
  - **the "number of sites" score should be 2 instead of 3, because the number of sites is less than 100.**

Regarding the technical dense polyurethanes with high specifications in industrial applications, the delays to change cannot be as short as for the industry of foam polyurethanes. For technical dense polyurethanes, the dependency of MOCA and the technical and economic constraints should absolutely be taken into account to avoid the loss of most of our clients (who may buy outside the European Union these products, some of which may even contain more MOCA than ours) or even the death of our group.

Elsewhere, within the technical dense polyurethanes, a difference can be made between the articles made with more or less MOCA. The former are harder and used for abrasion applications (with more potential exposures) with generally easier substitution potential (see table-2). We are much willing to implement changes but need time and consideration of the particularities among our technical dense polyurethanes.

Our request is so that ECHA differentiates in its recommendation delays in order to take into account the differences among technical dense polyurethanes, namely "hard" and "flexible" technical dense polyurethanes. Thus,

- **the recommendations should consider a medium term ("review period" at least of 6 years) economically viable for hard technical PU products made with a larger quantity of MOCA and which function is associated with mechanical resistance,**

- **and a longer term ("review period" at least of 12 years) allowing the R & D for flexible technical PU products made with a lower quantity of MOCA and which function is associated with elasticity.**

- **Lastly, 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 for which re-qualification of technical dense polyurethanes will be particularly complex and will so require much more time.**

Table-2: Summary of the request: dense technical polyurethanes should be differentiated from foam polyurethanes; and among the dense technical polyurethanes a difference can be made between the hard and flexible PU, the last requiring longer delays to implement technical and economical feasible substitutions.

Polyurethanes (PU)		**% MOCA** used in the process (but <1% w/w in the PU)	**Main function**	**Potential emission in environment**	**Substitution possibilities**	**Economical risk**	**Requested Review period, at least:**
~~Foam~~		~~Not concerned by our request~~					
Dense "technical"	Hard	12-20	mechanic	possible	difficult	losses	>6years
	Flexible	6-12	elastic	unimportant	Very difficult	bankruptcy	>12years

Appendix-1: A not exhaustive list of elements that Groupe COURBIS can adapt to industry needs.

Appendix-2: Result of analysis of MOCA in two typical elements produced by Groupe COURBIS.