ANNEX XV REPORT

AN ASSESSMENT OF WHETHER THE USE OF MOCA IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH ARTICLE 69(2) OF REACH

SUBSTANCE NAME: 4,4'-methylenebis[2-chloroaniline] (MOCA)

IUPAC Name: 4-[(4-amino-3-chlorophenyl)methyl]-2-chloroaniline

EC NUMBER: 202-918-9

CAS NUMBER: 101-14-4

CONTACT DETAILS:

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Contents

About the report

This draft report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006, which, after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), requires ECHA to consider if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepare an Annex XV restriction dossier.

In general, ECHA gathers information on potential risks to human health and/or the environment for identified uses of the substance in articles from various sources. Information is gathered (if available) from authorisations, recommendation for inclusion in Annex XIV and substance of very high concern (SVHC) identification. Uses identified in the REACH registrations, in substances in articles notifications in accordance with Article 7(2) of REACH[1] and the Waste Framework Directive (SCIP database[2]), are also investigated. Information on possible uses of the substance in articles that were not identified during the screening phase, can be gathered through a subsequent call for evidence launched via ECHA's website [last sentence to be changed once CfE has taken place, note that similarly some other parts need to be updated due to a reference to CfE].

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of this investigation. Incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH[3]. The incorporation process carried out in third countries is outside the scope of EU legislation. However, it should be noted that articles if imported to the EU are within the scope of this investigation. The incorporation is regarded to cover two type of uses[4]:

a) The substance is incorporated into an article during its production, or

b) The substance, alone or in a mixture is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g. coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

It is to be noted that there are several specific exemptions from the authorisation requirements[5], while only few exemptions are envisaged in case of restrictions. These include manufacture and

[1] Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details see: https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles.

[2] In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products): https://echa.europa.eu/scip.

[3] Q&A ID: 0564: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564 Note that ECHA will investigate for this report whether applications for authorisation/authorisation decisions cover the incorporation of the substance into an article and possible cumulative effects of the substance due to authorisations.

[4] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c

[5] https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products, and when a substance is used as an on-site isolated intermediate.

A. Conclusions

A.1 Conclusions based on the assessment

4,4'-methylenebis[2-chloroaniline] (MOCA) was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57 (a) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as carcinogen, Carc. 1B (H350: "May cause cancer") and was therefore included in the Candidate List for authorisation on 19 December 2011, following ECHA's decision ED/77/2011 with a sunset date of 22 November 2017.

ECHA has gathered information on the uses of MOCA from various sources. This includes information from authorisations, information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, uses identified in the REACH registrations, substances in articles (SiA) notifications and the SCIP database (Substances of Concern In articles as such or in complex objects (Products)) established under the Waste Framework Directive (2008/98/EC).

Following a preliminary assessment of the available evidence, ECHA considers that there are uses of the substance in articles that have the potential to lead to human exposure from MOCA in articles. MOCA is a non-threshold carcinogen for which no threshold can be determined below which exposure would be safe. Therefore, under Article 69(2), ECHA's preliminary view is that there may be a need to prepare an Annex XV dossier for restriction.

According to the applications for authorisations, the reported MOCA residual concentration is well below 0.1% (w/w) in the final articles produced in EU/EEA, where adequate technical measures are in place. It is unknown to ECHA if those technical measures are in place outside EU/EEA. According to the literature and other aforementioned sources, MOCA has been used in or discovered to be present in the following articles:

- Low-density flexible foam used in upholstery, bedding and automotive and truck seating
- Low-density rigid foam used for thermal insulation and RTM cores
- Soft solid elastomers used for gel pads and print rollers
- Low density elastomers used in footwear
- Hard solid plastics used as electronic instrument bezels and structural parts
- Flexible plastics used as straps and bands
- Durable elastomeric wheels and tires
- Automotive suspension bushings
- Electrical potting compounds
- Seals and gaskets
- Carpet underlay
- Hard plastic parts (such as for electronic instruments)
- Industrial rollers
- Conveyor belting

- Tensioner pads
- Spring blocks
- Punches, foils and battens for the ceramic industry
- Mining equipment
- Custom-made PU parts for a wide range of industries

This draft Article 69(2) report, including its preliminary conclusions, is subject to a call for evidence from 5 October 2022 to 16 November 2022. The call for evidence is launched to gather further information and comments on the assumptions made.

An Annex XV dossier for restriction according to Article 69(2) may be prepared taking into account the emerging priorities in the Restriction Roadmap including joint discussions with the Commission, ECHA and the Member States.

The assessment and conclusions are summarised in a final report, presented to CARACAL-Member States[6] as an information document.

A.2 Targeting

This report is targeted on the potential release of or exposure to MOCA from articles throughout their lifecycle (including the waste stage) and whether or not such use in articles should be restricted. The report is focused on human health hazards due to which the substance is placed on the Annex XIV. Other hazards are not taken into account in this report.

A.3 Summary of the justification

A.3.1 Identified uses, hazard, exposure / emissions and risk

Information on uses in articles

Current use of MOCA in the EU is limited to the uses within the scope of authorisation, unless exempted. Based on the information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, uses identified in the REACH registrations and information in the received applications for authorisation and other sources of information, MOCA is used primarily to produce polyurethane articles.

According to documents prepared in the context of ECHA's fourth Recommendation for the inclusion of substances in Annex XIV (ECHA 2012), professional uses have not been reported in the registration dossiers. However, it cannot be excluded that the substance is used by professionals in bi-component resins (resins + hardener) that are known to have been used earlier in construction and arts in the past (ECHA, 2011).

There are applications for authorisation submitted to ECHA. According to those applications, MOCA is used as curing agent, cross-linker and chain extender in polyurethanes for the manufacture of high-performance polyurethane products in a wide array of industries such as mining, minerals extraction and processing, paper and

[6] Competent Authorities for Registration, Evaluation, Authorisation and restriction of CHemicals (REACH) and Classification, Labelling and Packaging (CLP).

printing industry, packaging industry, fibre glass and glass manufacturing, steel and aluminium industries, oil and gas industry, textile and plastic industry, the wood and timber industry; in public transport, retail, motor vehicle manufacture, lifts and escalators, leisure industry and marine transport. Also, polyurethane parts are used in aerospace, industrial vehicles, energy (including renewables) and defence sectors.

Products made with a MOCA cured system include:

- Industrial rollers
- Wheels
- Belts used in many applications
- Tensioner pads
- Spring blocks
- Tubes
- Sheets
- Punches, foils and battens
- Custom-made PU parts for a wide range of industries

It was also specified that although professional uses of MOCA have occurred in the past (e.g. as hardener in arts and construction), those were excluded from the scope of the applications for authorisations solely covering the industrial use.

Article service life or consumer exposure were not considered by the applicants. According to the applications for authorisation, MOCA is reacted with the prepolymer system (a blend of liquid isocyanates, liquid polyols, catalysts and other additives) and the resulting polyurethane is cast to moulds that are then cured in ovens. MOCA is used as an additive with the purpose to give the resulting polymer specific properties (ECHA 2011) such as abrasion and cut resistance, humidity, hydrolysis, heat, tear resistance, UV resistance, ozone resistance, and resistance to radiation and fire retardant properties. Thus, it provides mechanical strength, high dynamic performance, long product lifetimes and/or adhesion.

According to the Chemical Safety Reports (CSR) provided by the registrants in the IUCLID dossiers, MOCA-containing polyurethane products have many uses, the majority in the form of foams, with flexible and rigid types being roughly equal in market size. The following applications have been identified:

- Low-density flexible foam used in upholstery, bedding and automotive and truck seating
- Low-density rigid foam used for thermal insulation and RTM cores
- Soft solid elastomers used for gel pads and print rollers
- Low density elastomers used in footwear
- Hard solid plastics used as electronic instrument bezels and structural parts
- Flexible plastics used as straps and bands
- Durable elastomeric wheels and tires
- Automotive suspension bushings
- Electrical potting compounds
- Seals and gaskets
- Carpet underlay
- Hard plastic parts (such as for electronic instruments)

Nevertheless, there are no substance in articles (SiA) notifications submitted to ECHA. This might be due to the fact that only trace amounts are reported as residual concentration of MOCA in the articles cured with this substance. However, it also could be because quantities of MOCA in those articles do not total over one tonne per producer or importer per year or a combination of both conditions. According to the applications for authorisations, the reported MOCA residual concentration is well below 0.1% (w/w) in the final articles produced in EU/EEA, where adequate technical measures are in place. It is unknown to ECHA if those technical measures are in place outside EU/EEA. Where adequate technical measures are not in place, the reported MOCA residual concentration may be close to 0.1% (w/w) or even higher.

In addition, the information available in the SCIP database indicates reported residual concentration well above 0.1% (w/w). The SCIP notification duty covers all articles placed on the EU market (including imported articles) containing a substance in the Candidate List in concentrations above 0.1% w/w. Despite the fact that no SiA notification were submitted to ECHA under REACH, the SCIP database contained a significant number of notifications identifying the presence of MOCA in a concentration above 0.1% in articles as such or in complex products. In particular in the following categories:

- Components and accessories for optical, photographic, cinematographic, measuring, checking, precision, medical or surgical machines, appliances, instruments or apparatus, including therapeutic respiration, electrodiagnostic, and computed tomography apparatus
- Electromechanical domestic appliances, electrical machines and apparatus, and components thereof, including coaxial cables and insulated electric wires
- Industrial robots, machine tools including components thereof and accessories, components of boilers, machinery and mechanical appliances with spark-ignition internal combustion piston engines, components and accessories of combustion piston engines, sewing machines, office machines and other machinery and mechanical appliances
- Unspecified plastic articles
- Components and accessories of the motor vehicles, namely gear boxes and components thereof, and of vehicles not mechanically propelled such as trailers and semi-trailers

Some data in the SCIP database further identify the presence of MOCA in a concentration above 0.1% (w/w):

- incorporated during production from the use of adhesives and sealants (mixtures), namely in assembly line processes, in components and accessories of the motor vehicles, namely gear boxes and components thereof; rear-view mirrors for vehicles; appliances for pipes, boiler shells, tanks, vats or the like; components and accessories for instruments and apparatus for measuring or checking the flow, level, pressure of fluids; and other articles;
- in articles made of polyurethanes in industrial robots, machine tools including components thereof and accessories, components of boilers, spark-ignition internal combustion piston engines, sewing machines, office

machines such as printers and their components and accessories, and other machinery and mechanical appliances;
- in components and accessories of the motor vehicles made of epoxide resins; and
- in rubber articles made of polyurethane rubber as well as in components and accessories of vehicles not mechanically propelled such as trailers and semi-trailers made of rubber.

The use the substance in articles may be continuing internationally and articles containing the substances in a concentration exceeding 0.1% w/w may be placed on the EU market in quantities of less than one tonne of the substance per year per supplier, as evidenced by submissions to the SCIP database (and the absence of notifications to the SiA database).

Information on hazards

MOCA is included in Annex XIV based on its carcinogenic properties (Carc. 1B – Article 57a). In the evaluation of the scientific relevance of occupational exposure limits (OELs) for MOCA, the Committee for Risk Assessment (RAC) concluded in 2017 that a health-based OEL cannot be assigned to MOCA because it is considered a non-threshold genotoxic carcinogen with respect to risk characterisation (ECHA 2017).

Other endpoints are not relevant for this report.

MOCA is classified in Annex VI of CLP as: Acute Tox. 4 (H302), Carc. 1B (H350), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

Information on release/exposure

MOCA is a liquid with a low vapour pressure of 0.17 Pa at 60 °C. It is mainly used in the production of high-performance polyurethane products.

Polyurethane products are produced both in manual and automated moulding processes. Exposure at industrial sites may occur during transfer of MOCA (PROC 8a, 8b and 9), melting of MOCA and transferring to mixing recipient (PROC 5), pouring of polyurethane mixture to moulds (PROC 4), curing in oven of polyurethane mixture (PROC 23) and maintenance and cleaning of equipment (PROC 28).

MOCA is highly reactive in the prepolymer system and consequently, it might be present in the end-product (articles) as an impurity in traces only. One of the applicants reported that according to powdering test results reported in surveys, MOCA concentration ranged from 0.002-0.01% w/w in the finished articles tested and 0.000025-0.00021% in surface tests.

According to the CSR provided by the lead registrant in its dossier (CSR 2014) a total amount of 0.36 tonnes/year can theoretically end up completely in EU consumer household articles. However, considering the information provided in the applications for authorisation this tonnage might not reflect the current situation. In addition, it is stated that considering the low vapour pressure of MOCA, the release from articles is at most 1% per year via degassing into air and dermal contact is considered to be precluded based on the substance being enclosed in the article product matrix. Nevertheless, no information on leaching was provided, and the justification relies on the available physico-chemical properties (low water solubility and moderate soil

adsorption) that tend to indicate that the substance would stay within the polymeric matrix.

ECHA did not receive any SiA notification of MOCA in articles under REACH. However, the information available in the SCIP database indicates reported residual concentrations since the notifications identify the presence of MOCA in articles in concentrations above 0.1%

Characterisation of risk

MOCA is considered to be a genotoxic carcinogen. No threshold can be determined below which exposure would be safe. The reference dose response relationship established by RAC for carcinogenicity of MOCA (RAC, 2015) for inhalation, dermal and oral route, has to be considered. RAC also concluded that the major exposure route for MOCA is the dermal route.

As no safe threshold limit can be established, it is considered that any presence of MOCA in articles, potentially poses a risk and should be further investigated. A search of the SCIP database for MOCA indicate there are articles in the EU containing the substance used in vehicles, electric appliances (including domestic) and industrial machinery among others. This information confirms that there are articles (probably imported articles) that contain the substance in concentrations well above 0.1% as a residue. This content of MOCA in articles can lead to significant human exposure to a substance that is a non-threshold carcinogen and consequently to a possible unacceptable risk for human health.

According the Annex I paragraph 6.5, ECHA guidance Part E (ECHA, 2016) and R.8 (ECHA, 2012) and the 'Common approach of RAC and SEAC in opinion development on applications for authorisation', the adequate control route is not possible for a non-threshold substance (such as MOCA). Similarly, when a substance is present in articles, the releases of the substance from articles / exposure of the substance when present in articles may cause a risk.

This section will be updated after the call for evidence.

According to RAC, MOCA is a carcinogenic substance for which no safe threshold can be derived. RAC derived the lifetime cancer risk for 1 unit for workers and the general population as follows:

Route of exposure	Population	Cancer risk for 1 unit amount
Oral	General population	9.43×10^{-5} per µg/kg bw/day
Inhalation	Workers	9.65×10^{-6} per µg/m^3
	General population	5.43×10^{-5} per µg/m^3
Dermal	Workers	3.38×10^{-5} per µg/kg bw/day

No lifetime cancer risk was derived for the general population via dermal route.

A.3.2 Justification that action is required on a Union-wide basis

A Union-wide action is proposed due to the identification of possible unacceptable risk for human health that require to be addressed at the European level and the lack of existing EU wide measure to address the identified risks. To this effect, a restriction of MOCA from articles is proposed.

Based on the following reasons, a Union-wide action to address the risks associated with EU manufactured or imported articles containing MOCA seems warranted:

- To ensure a harmonised high level of protection of human health across the Union;
- To ensure the free movement of goods within the Union, where relevant.

A.2.3 Justification that the proposed restriction is the most appropriate Union-wide measure

As carcinogen category 1B substance, MOCA is prohibited for the use in toys and restricted for supply to the general public (in its own and in mixtures) by entries 28-30 of Annex XVII. There are no restrictions in articles other than in toys.

There are currently no EU measures in place to protect humans from the risk of imported articles other than toys containing MOCA. Therefore, a restriction on the content or release of MOCA from articles is proposed.

A restriction on the placing on the market of articles containing MOCA for all populations (general public, professional and industrial workers) would allow a high level of protection of human health with limited expected socio-economic impacts in the EU. To the extent known so far, MOCA is only present in the articles in residual amounts from the article manufacturing process in the EU. The whole justification will be elaborated in the possible future restriction proposal.

B. Information on hazard and risk

B.1 Identity of the substance and physical and chemical properties

B.1.1 Name and other identifiers of the substance

4,4'-methylenebis[2-chloroaniline] (MOCA)

Chemical name: 4,4'-methylenebis[2-chloroaniline]

EC Number: 202-918-9

CAS Number: 101-14-4

IUPAC Name: 4,4'-Methylenebis(2-chloroaniline)

B.1.2 Composition of the substance(s)

4,4'-methylenebis[2-chloroaniline] (MOCA)

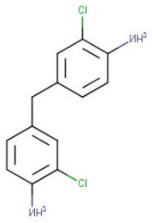
Chemical name: 4,4'-methylenebis[2-chloroaniline]

EC number: 202-918-9

CAS number: 101-14-4

IUPAC name: 4,4'-Methylenebis(2-chloroaniline)

Molecular formula: C13 H12 Cl2 N2

Structural formula: 

Molecular weight: 267.2 g/mol

Typical proportion %: 88% (w/w)

Concentration range %: >86.7 - <93.2% (w/w)

B.1.3 Physicochemical properties

Table 1 provides certain physicochemical properties for MOCA. ECHA's dissemination site provides further information as provided by the registrants.

TABLE 1 Selected physicochemical properties

REACH ref Annex	Property	Value
VII, 7.1	Physical state at 20°C and 101.3 kPa	Light yellow granular solid with amine odour
VII, 7.2	Melting/freezing point	110 °C
VII, 7.3	Boiling point	Decomposing prior boiling at 370 °C
VII, 7.4	Relative density	1.44 g/cm3 at 24 °C
VII, 7.5	Vapour pressure	0.17 Pa at 60 °C
VII, 7.6	Surface tension	73.3 mN/m (90% saturation solubility at 20 °C)
VII, 7.7	Water solubility	13.8 mg/l at 20 °C; pH = 7.6
VII, 7.8	Partition coefficient n-octanol/ water (log value)	2.5 at 25 °C and pH ca. 7
VII, 7.16	Dissociation constant (pKa)	2.27 and 3.41
VIII, 9.3.1	Adsorption coefficient (log value)	3.56 at 35 °C

Sources: SVHC support document for MOCA (ECHA, 2011) and CSR (2014)

B.1.4 Justification for grouping

Not relevant.

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of a substance

MOCA is manufactured by reaction of formaldehyde and 2-chloroaniline (IARC, 2010). However, MOCA is not manufactured in Europe according to the Annex XV report (ECHA, 2011). The import at the time has been between 1,000 – 10,000 t/y (aggregated registration information). Less than 100 t/y are exported (ECHA, 2011). According to the current information on ECHA's website the substance is manufactured in and / or imported to the EU/EEA area between 100-1000 t/y, however the latest updates of the registrations are from 2012.

B.2.2 Uses in articles

Information from REACH applications for authorisation

Since MOCA is a substance on the authorisation list, uses of the substance after the sunset date (22 November 2017) are only allowed in the EEA if an authorisation has been granted for these uses, unless exempted. To date (Day Month Year), 3 applications

for authorisation have been submitted to ECHA. No authorisation decisions have yet been adopted. According to those applications, MOCA is used as curing agent, cross-linker, and chain extender in polyurethanes for the manufacture of a wide variety of high-performance polyurethane products.

According to these applications for authorisation MOCA is highly reactive in the prepolymer system and consequently, it might be present in the articles as an impurity in traces only.

TABLE 2 Information on applications for authorisation for uses of MOCA[7]

Applicant(s)	Applied use(s)	Tonnage per year	Incorporation in articles	Date of expiry of review period	Date of submission of review report	Review decided
REACHLaw Ltd (Only Representative for Suzhou Xiangyuan Special Fine Chemical Co., Ltd)	Industrial use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production	516	Article category: AC 0: Other (non-intended to be released). Impurity within polyurethane products			
Limburgse Urethane Castings NV	Industrial use of MOCA in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors Industrial use of MOCA in the manufacture of high-performance polyurethanes specifically for heavy-duty rollers, tensioner pads and spring blocks with high reliability requirements for offshore energy and renewables	44.3	No article category. Impurity within polyurethane products			

[7] Search done 25 February: https://ec.europa.eu/docsroom/documents/44775 and https://echa.europa.eu/applications-for-authorisation-previous-consultations

	sectors					
Courbis Synthèse; Annovi S.r.l.; Dansk Elastomer A/S; Durlast S.r.l.; Pieffe S.r.l.; Policart S.r.l.; R.B.M. Italia S.r.l.; Tecnocaucho S.A.; Tegea S.r.l.; Optibelt Urethane Belting Ltd.; Productos Salinas S.A.; V.M. SPA	Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of hot cast polyurethane products	142-239	No article category. Impurity within polyurethane products			

According to the REACHLaw application, MOCA is used for the manufacture of high-performance polyurethane products in a wide array of industries such as mining, minerals extraction and processing, paper and printing industry, packaging industry, fibre glass and glass manufacturing, steel and aluminium industries, oil and gas industry, textile and plastic industry, the wood and timber industry; in public transport, retail, motor vehicle manufacture, lifts and escalators, leisure industry, and marine transport. Also, parts are used in aerospace, industrial vehicles, energy (including renewables) and defence sectors.

Products made with a MOCA cured system includes:

- Industrial rollers
- Wheels
- Belts used in many applications
- Tensioner pads
- Spring blocks
- Tubes
- Sheets

Information from substance in articles (SiA) notifications

There are no substance in articles notifications made under Article 7(2) for MOCA. This can be due to the reported MOCA residual concentration being (well) below 0.1% (w/w) in the articles cured with MOCA. However, it also could be because quantities of MOCA in those articles do not total over one tonne per producer or importer per year or a combination of both conditions.

Information from the SCIP database

The SCIP notification duty covers all articles placed on the EU market (including imported articles) containing a substance in the Candidate List in concentrations above

0.1% w/w. The SCIP database contained a significant number of notifications identifying the presence of MOCA in a concentration above and well-above 0.1% in articles as such or in complex objects. In particular in the following categories:

- Components and accessories for optical, photographic, cinematographic, measuring, checking, precision, medical or surgical's machines, appliances, instruments or apparatus, including therapeutic respiration, electrodiagnostic, and computed tomography apparatus
- Electromechanical domestic appliances, electrical machines and apparatus, and components thereof, including coaxial cables and insulated electric wires
- Industrial robots, machine tools including components thereof and accessories, components of boilers, machinery and mechanical appliances with spark-ignition internal combustion piston engines, components and accessories of combustion piston engines, sewing machines, office machines and other machinery and mechanical appliances
- Not specified plastic articles
- Components and accessories of the motor vehicles, namely gear boxes and components thereof, and of vehicles not mechanically propelled such as trailers and semi-trailers

Some data in the SCIP database further identify the presence of MOCA in a concentration above 0.1% (w/w):

- incorporated during production from the use of adhesives and sealants (mixtures), namely in assembly line processes, in components and accessories of the motor vehicles, namely gear boxes and components thereof; rear-view mirrors for vehicles; appliances for pipes, boiler shells, tanks, vats or the like; components and accessories for instruments and apparatus for measuring or checking the flow, level, pressure of fluids; and other articles;
- in articles made of polyurethanes in industrial robots, machine tools including components thereof and accessories, components of boilers, spark-ignition internal combustion piston engines, sewing machines, office machines such as printers and their components and accessories, and other machinery and mechanical appliances;
- in components and accessories of the motor vehicles made of epoxide resins; and in rubber articles made of polyurethane rubber as well as in components and accessories of vehicles not mechanically propelled such as trailers and semi-trailers made of rubber.

Information from REACH registration dossiers

MOCA is mainly used in the production of high-performance polyurethane products. Polyurethane production is performed in closed system with no likelihood of exposure.

In the CSR of the lead registration dossier many uses have been identified for MOCA-containing polyurethane products, the majority in the form of foams, with flexible and rigid types being roughly equal in market size. The following applications have been identified:

- Low-density flexible foam used in upholstery, bedding and automotive and truck seating
- Low-density rigid foam used for thermal insulation and RTM cores
- Soft solid elastomers used for gel pads and print rollers
- Low density elastomers used in footwear
- Hard solid plastics used as electronic instrument bezels and structural parts
- Flexible plastics used as straps and bands
- Durable elastomeric wheels and tires
- Automotive suspension bushings
- Electrical potting compounds
- Seals and gaskets
- Carpet underlay
- Hard plastic parts (such as for electronic instruments)

From the active registration dossiers, the following types of uses were identified:

Uses at industrial sites:

- Use as curative in a chemical reaction with pre-polymers – hot cast PU processing
- Use of polyurethane in the manufacture of finished articles

No professional uses were reported

No consumer uses were reported

Currently the uses for which the application for authorisation has been submitted are allowed, unless exempted from authorisation. Any other uses in articles identified in the CSR can be seen as historical uses in EU. These articles, however, may be imported into the EU/EEA. In fact, even though no SiA notifications have been made, information available from SCIP database for MOCA indicate there are articles in the EU containing the substance used in vehicles, electric appliances (including domestic) and industrial machinery among others in concentrations well above 0.1%. Call for evidence will be used to gather further information on the uses in articles identified so far and whether other uses exist.

Information from databases

Several databases[8] were searched but not specific information on uses of a substance in articles reported.

Based on the above information on applications for authorisations, the production of the articles in the EU/EEA leads only to trace levels of MOCA in articles. However, whether the technical measures decreasing the concentrations of MOCA implemented by the applicants are in place outside EU/EEA is not known to ECHA. Where adequate technical measures are not in place the reported MOCA residual concentration may be close to 0.1% (w/w) or even higher. The numerous SCIP notifications of articles seem to indicate

[8] Danish Chemicals in Consumer Products, Consumer Product Information Database, EPA comptox, OECD global product recalls, Children's Safe Product Act Reported Data, Crest search engine, Chemsec sinlist, IARC monographs, Pesticides in CA, SPIN

that there are articles containing more than 0.1% MOCA that are imported to the EU/EEA.

B.2.3 Uses advised against by the registrants

There are uses advised against in the registrations in a general form. The registrants state that they advise against uses other than the ones identified in the registration dossier.

B.2.4 Description of targeting

This restriction report is targeted on the potential release of MOCA from articles and exposure of MOCA when used in articles and whether or not such use should be restricted. Furthermore, targeting is based on the hazard for which the substances was included on Annex XIV, i.e. carcinogen Cat. 1B.

B.3 Classification and labelling

Classification according to CLP

The harmonised classification of MOCA according to CLP is presented in the table below.

Index #	EC #	Classification	Specific Conc. Limits, M-factors	Notes	ATP inserted/ updated
612-078-00-9	202-918-9	Acute Tox. 4 (H302) Carc. 1B (H350) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	/	/	CLP00

Classification according to the Classification and Labelling Inventory

There have been 231 notifications to the C&L inventory for MOCA most of them reproducing the harmonised classification. Some of them have a lower hazard class for certain endpoints or they are deviating e.g. on the pictograms. 63 notifications cover an additional endpoint of Muta. 2; H341.

B.4 Environmental fate properties

Not relevant

B.5 Human health hazard assessment

MOCA has a harmonised classification as Carc. Cat 1B (H350) according to CLP. In the evaluation of the scientific relevance of occupational exposure limits (OELs) for MOCA, RAC concluded that a health-based OEL cannot be assigned to MOCA because it is considered a non-threshold genotoxic carcinogen with respect to risk characterisation (ECHA, 2015).

IARC (2010) reported strong evidence of the carcinogenicity of MOCA via a genotoxic mechanism of action. The data suggest that the genotoxic mechanism includes metabolic activation of MOCA to form adducts with DNA, resulting in the induction of mutagenic and clastogenic effects in humans. No threshold can be determined below which exposure would be safe.

Lung, liver and bladder cancers are identified as the key cancer risk endpoints for exposure to MOCA.

B.6 Human health hazard assessment of physicochemical properties

Not relevant

B.7 Environmental hazard assessment

Not relevant

B.8 PBT and vPvB assessment

Not relevant

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

For this report only releases and exposure from articles are relevant.

The major exposure route for MOCA is the dermal route. Although unreacted MOCA may be present in final articles which could lead to exposure, there are technical means in place at industrial sites in EU/EEA to minimise the content of free MOCA in articles and thus, the reported MOCA residual concentration is (well) below 0.1% (w/w) (ECHA, 2011; RCOM, 2011; RCOM, 2012). This is also indicated in the application for authorisations.

Nevertheless, where adequate technical measures are not in place the reported MOCA residual concentration may be close to 0.1% (w/w) or even higher. The SCIP database contained a significant number of notifications identifying the presence of MOCA in a concentration above and well-above 0.1% in articles as such or in complex objects. This may indicate that articles containing MOCA in significant concentration are imported to the EU/EEA.

B.9.1.1 Summary of the existing legal requirements

REACH has several requirements for substances on the candidate list including notification of its presence in articles if $\geq$0.1% and 1 tonne per year (Article 7(2)) and that suppliers must inform their customers on request if an article contains more than 0.1% by weight of MOCA (Article 33(b)). No SiA notifications have been made for MOCA.

In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% by weight on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of

Concern In articles as such or in complex objects (Products): https://echa.europa.eu/scip.

The entries in Annex XIV for MOCA Authorisation set a last application date of 22/05/2016 and a sunset date of 22/11/2017.

Information on existing legislations in European Union relevant for MOCA is available on ECHA's website under EU Chemicals Legislation Finder (EUCLEF): https://echa.europa.eu/legislation-obligation/-/obligations/100.002.654

B.10 Risk characterisation

MOCA is considered to be a genotoxic carcinogen. No threshold can be determined below which exposure would be safe. The reference dose response relationship established by RAC for carcinogenicity of MOCA (RAC, 2015) for inhalation, dermal and oral route, has to be considered. RAC also concluded that the major exposure route for MOCA is the dermal route.

As no safe threshold limit can be established, it is considered that any presence of MOCA in articles potentially poses a risk and should be further investigated. A search of the SCIP database for MOCA indicate there are articles in the EU containing the substance used in vehicles, electric appliances (including domestic) and industrial machinery among others. This information seems to confirm that there are articles (probably imported articles) that contain the substance in concentrations well above 0.1%. This residual content of MOCA in articles can lead to significant human exposure to a substance that is a non-threshold carcinogen and consequently to a possible unacceptable risk for human health.

According to the Annex I paragraph 6.5 of the REACH Regulation, ECHA guidance Part E (ECHA, 2016) and R.8 (ECHA, 2012) and the 'Common approach of RAC and SEAC in opinion development on applications for authorisation', the adequate control route is not possible for a non-threshold substance (such as MOCA). Similarly, when a substance is present in articles, the releases of the substance from articles / exposure of the substance may cause a risk

According to RAC, MOCA is a carcinogenic substance for which no safe threshold can be derived. RAC derived the lifetime cancer risk for 1 unit for workers and the general population as follows:

Route of exposure	Population	Cancer risk for 1 unit amount
Oral	General population	9.43×10^{-5} per µg/kg bw/day
Inhalation	Workers	9.65×10^{-6} per µg/m^3
	General population	5.43×10^{-5} per µg/m^3
Dermal	Workers	3.38×10^{-5} per µg/kg bw/day

No lifetime cancer risk was derived for the general population via dermal route.

This section will be updated after the call for evidence.

C. Available information on alternatives

Industry acknowledges the availability of alternative curing products but also claims that the final products produced with the alternatives will not have as good properties as the MOCA based ones. This lack of performance is considered the main factor limiting the use of the alternative curing agents. However, costs may as well be a limiting factor as such alternative curing agents are more expensive than MOCA.

The Annex XV report (ECHA, 2011) lists several of these substances or substance groups, such as other aromatic amines, aliphatic amines or isobutylesters that can be used as alternative curing agents although their suitability would need to be assessed for each specific application.

D. Justification for action on a Community-wide basis

A Union-wide action is proposed due to the identification of possible unacceptable risk for human health that require to be addressed at the European level and the lack of existing EU wide measure to address the identified risks. To this effect, a restriction of MOCA from articles is proposed.

Based on the following reasons, a Union-wide action to address the risks associated with EU manufactured or imported articles containing MOCA seems warranted:

- To ensure a harmonised high level of protection of human health across the Union;
- To ensure the free movement of goods within the Union, where relevant.

E. Justification why the proposed restriction is the most appropriate Community-wide measure

As carcinogen category 1B substance, MOCA is prohibited for the use in toys.

There are currently no EU measures in place to protect humans from the risk of imported articles (other than toys) containing MOCA. Therefore, a restriction on the content or release of MOCA from articles is proposed.

A restriction on the placing on the market of articles containing MOCA for all populations (general public, professional and industrial workers) would allow a high level of protection of human health with minimal expected socio-economic impacts. To the extent known so far, MOCA is only present in the articles as an impurity from the article manufacturing process.

F. Socio-economic Assessment of Proposed Restriction

To be developed after the call for evidence or when restriction proposal is prepared.

G. Stakeholder consultation

The draft Annex XV report is subject to a Call for evidence from 5 October 2022 to 16 November 2022 (6 weeks).

H. Other information

Not relevant.

References

The applications for authorisation received by ECHA on MOCA are available at https://echa.europa.eu/applications-for-authorisation-previous-consultations

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