Application for the Authorisation of Continued use of Methylene Bis Ortho Chloro Anilene (Mboca) in an Industrial Setting (Hot Polyurethane Casting)

Article 62 of UK REACH Regulation (EC) No 1907/2006.

Substance Information:

Name(s)	Methylene Bis Ortho Chloro Anilene (Mboca) 2,2'-dichloro-4,4'-methylenedianiline (MOCA) For this application the term **Mboca** will be used
EC Number	202-918-9
CAS Number	101-14-4
Entry Nr in Annex XIV	27
General information on use	Bonaprene uses Mboca as a reactant in the manufacture of cast polyurethanes at industrial sites. Mboca is entirely consumed in the manufacturing process and the resulting polyurethanes are Mboca free. The polyurethanes are supplied to different sectors e.g., offshore energy, industrial automation as components that are integrated into transport systems, industrial installations and machines (e.g. roller, pads, wheels, anvil covers, power transmission belts). The cast polyurethanes need to fulfil strict technical requirements that are set by customers/or required by the end use.
Total annual material consumption by the applicant	3,200kg and declining

This application is being submitted by Richard Mills Production Director for **Bonaprene Products Limited**, Clywedog Road South, Wexham Industrial Estate, Wrexham. North Wales. UK LL13 9XS 019478667721 / 01973271037

Contents

List of abbreviations	Full name	Comments
COSHH	Control of substances hazardous to Health	
FPK	Full Protective kit	A set of PPE particular to the applicant
LEV	Local Exhaust Ventilation	
Mboca	Methylene Bis Ortho Chloro Anilnene	
Mdi	Di Phenyl Methane Di-isocyanate	
NOCN	Nation Open College Network	
NVQ	National Vocational Qualification	
PPE	Personal Protective Equipment	
PU	Polyurethane	
PUPMT	Polyurethane Product Manufacturing Technology	AN NVQ III equivalent training program accredited by NOCN
Tdi	Toluene Di-isocyanate	The principal pre-polymer used in conjunction with Mboca

Uses Applied for, Conditions of Use and Function

Mboca is used as a reactant in the manufacture of cast polyurethanes at industrial sites. Mboca is entirely consumed in the manufacturing process and the resulting polyurethanes are Mboca free. The polyurethanes are supplied to different sectors e.g., offshore energy, industrial automation as components that are integrated into transport systems, industrial installations and machines (e.g. steel mill rollers, pads, wheels, hydro-cyclones, quarry scrapers). The cast polyurethanes need to fulfil strict technical requirements that are set by customers / or required by the end use. The applicant is actively engaged in substitution and this application covers system formulations where alternatives are not suitable for technical and economic reasons.

The Tdi - Mboca system gives high quality polyurethanes with a range of properties that can be tailored for the end use. It has several well-known advantages, which is why Tdi -Mboca is still widely used outside of the EEA. Its advantages include an unsurpassable quality to cost ratio, adaptable and flexible PU system for the production of very diverse PU products, long pot-life suitable for casting polyurethanes of different size and it is associated with very low scrap rates.

The applicant tests new system formulations as they become available._The applicant is not in the business of chemical manufacture so they actively collaborate with suppliers and alternative providers to find alternatives. However, none of the tested alternatives have proved to be suitable to replace Mboca in the products covered by this application at the time of submission. It is currently uncertain when a suitable Mboca-free chain extender and / or alternative system that can produce polyurethanes that fulfil the PU processors' requirements in terms of product performance, processability, pot-life and costs will be available on the market. Even if a suitable alternative were to become available, the successful substitution of Mboca will take several years. Many products have not 'proved' themselves until they have demonstrated a longevity of up to four or five years. The PU processors have indicated they would need at least 7 years to substitute Mboca starting from 2022. It should be noted that the cast PU market is highly competitive and global. TDI/ Mboca is still widely used outside of the EEA / UK and with the absence of restriction on imports of Mboca -based products from outside the UK, the home PU market is distorted, rendering the substitution of Mboca complex for the applicant.

Risk Assessment and Limitation to use as only for Replacement Parts

As Mboca is a legacy substance it has been relatively easy over recent years to restrict its use to replacement parts. This has been controlled by incorporating this into the applicants' Risk Assessment for Mboca Handling and Processing RA23 Issue 12 (Recently updated for the benefit of this application) This RA is repeated in full below: This assessment also gives a good insight to the applicants' handling processing and safety procedures.

RA 23 RISK ASSESSMENT FOR Mboca Handling and Processing AT BONAPRENE PRODUCTS LTD (Methylene Bis-ortho chloro analine)

The primary action to reduce risk is not to use Mboca wherever an alternative resin system is available. This has been achieved for some 96% of all PU production. The table below outlines those product groups which are currently still cast using Mboca. Where Mboca is still used, it is limited to 'replacement parts' and not new products.

Product Description	Application
Miscellaneous Large Roller Recovery including Steering & Dolphin Rollers	Recovery of existing rollers which are too large to be recovered using dispensed quasi-MDI or require superior performance. Currently investigating 'ribbon flow' alternatives.
Porvair – ISO Bags	Replacement parts where customer unwilling to try alternatives
Valmet Cyclones	Replacement parts only fitted to very old paper mills
Various Wheels	Replacement parts, though each job is reviewed as non Mboca cured alternatives are often possible
Various Curved Scrapers	Spare replacement parts giving superior performance to alternatives. Replacement parts, though each job is reviewed as non Mboca cured alternatives are often possible
Various sheets	Miscellaneous replacement parts, though each job is reviewed as non Mboca cured alternatives are often possible
e-log tubes	Part used in equipment to log boreholes in many renewable applications. Superior processability to alternatives.
Various PU Moulds	Replacement PU Mould which degrades with heat and use. Life expectancy of Mboca cured moulds is significantly greater than other alternatives. Where possible, PU moulds are increasingly being replaced with CNC machined aluminium moulds.

Mboca granules are stored in the sealed well labelled kegs which it is bought in. These are securely wrapped in film and stored on pallets within the factory.

All personnel handling or processing either the kegs, granules. melted Mboca or the mixed uncured TDI resin will at all times wear full PPE as detailed on COSHH002 High Hazard Substance - 002 – Mboca. Peculiar to Bonaprene and the use of Mboca, PPE is known as FPK. Please see PUPMT training programme for full description of FPK

From storage the kegs are removed from the pallet and securely mounted in a specially designed forklift cage, prior to the keg lid being un-sealed and being tipped into the Mboca Hopper.
The individual driving the forklift must also be wearing full FPK / PPE, but will not touch or unseal the keg.

A full keg will always be emptied into the hopper by the individual wearing full FPK who previously unsealed said keg. There is LEV extraction around the top of the hopper, so any minimal quantity of Mboca powder which becomes airborne when emptying the keg into the hopper will immediately be extracted.

Kegs and lids disposed of in hazardous waste.
Mboca powder is dropped from the hopper into a heated vat below within a fume / dust extracted booth, via a portcullis valve. The heated vat is controlled via a 24/7 timer such that it only melts the Mboca (creates fumes) when the main factory LEV extraction is on. The vat heating is switched off before the LEV extraction to give time for the Mboca to freeze and so there is no chance fumes are released into the factory.

Melted Mboca is dispensed from the vat via a manually operated valve to a 5L pail or bucket on scales, The correct weight is then mixed with TDI resin nearby, with LEV also present above said mixing station, before being poured into a mould. Once the resin has cured, the Mboca ceases to exist, having chemically reacted to become part of the TDI polyurethane product. It then becomes safe to handle without PPE

HAZARD	RISK CATEGORY	TO WHOM	ACTION TO REDUCE RISK
Mboca powder or melted Mboca causing skin irritation or burns	5	Caster	Full PPE as detailed on COSHH002 High Hazard Substance - 002 – Mboca to be worn by all individuals working in vicinity
Mboca powder becoming airborne and inhaled	5	Caster	Full PPE as detailed on COSHH002 High Hazard Substance - 002 – Mboca to be worn by all individuals working in vicinity LEV extraction is applied in all areas where Mboca powder is disturbed
Mboca fumes being inhaled	5	Caster	Full PPE as detailed on COSHH002 High Hazard Substance - 002 – Mboca to be worn by all individuals working in vicinity LEV extraction is applied in all areas where melted Mboca is handled

Mitigation, Measurement and Control

Mboca can be absorbed through the skin, the mouth or inhalation. To mitigate this risk the measures above are always in place. ALL staff are inculcated to be vigilant about their personal hygiene and use barrier creams. Signs are displayed around the building and especially in the locker / wash rooms.
The UK HSE set a limit for detecting Mboca in the body at 15 nano molecules of Mboca per milli molecule of Creatine. (Creatine is a constant in the urine regardless of hydration levels) The target at Bonaprene is **zero**. To this end six monthly urine checks are carried out on all personnel involved with handling Mboca. Annual checks are conducted on other staff as a control and a further safety check.
Amine detecting surface swipe tests are caried out annually to ensure that there is no build up on work surfaces

ASSESSMENT UNDERTAKEN

SIGNED *Richard Mills*

DATE **9/3/22**

Annual tonnage used: at maximum 3.2 tonnes and declining

Sector of end use (SU): 0
Environmental release category (ERC): 6d
Process category (PROC): 1, 3, 4, 8b, 23, 28
Product category (PC): 32
Article category related to subsequent service life (AC): N/A
Technical Function: Curing agent/Chain extender

Chemical Safety Report

In accordance with Annex I covering the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV

Occupational exposure to Mboca is regulated in many European countries and national occupational exposure limits range between 5 µg/m3 to 220 µg/m3 . An entry for Mboca has been included in Annex III to the Carcinogens and Mutagens Directive (CMD) (Directive 2004/37/EC) - carcinogens or mutagens at work

The applicant considers 'None detected' is the only acceptable result from biomonitoring. Please see attached ecological test results and an extract for the companies accredited (NOCN) training program.

All Casting staff (The only operators or handlers of Mboca) are put through an extensive practical, written and examined training program. This program is externally moderated and records are kept indefinitely. It covers all aspects of working with Mboca; storage, usage / processing, spillage, fire precautions and extinguishing and Frist Aid

Extract 1: from Polyurethane Product Manufacturing Technology NVQ III training program:

At various points in the programme, we shall refer to "Full Protective Kit". What we mean by this is as follows: -

Elastic cuff overalls (buttoned or zipped up at the front) Rigger and rubber liner gloves (ensuring a good "seal" over the overalls at the wrist), steel toe capped boots with the tops inside the overall trouser ends and fully functioning Airflow (Jupiter) helmet with the visor **down.** Safety glasses must also be worn with the helmet. This is due to a near miss report that arose from an operative working with hot MEK that splashed into his eyes while the visor was raised.

There is a version of FPK for use in fire or fire risk conditions known as FPK (fire). Nylon overalls are replaced by cotton ones and leather gloves replace rubber gloves. This is because natural materials, such as cotton and leather, are generally much more resistant to fire than man-made ones, such as nylon and rubber.

In circumstances where it has been deemed to be safe and for the sake of comfort a reduced form of FPK may be worn. To be known as Partial Protective Kit (PPK) it consists of protective arm sleeves in place of the full overalls and the Jupiter helmets need not be worn though safety glasses MUST be. Gloves and boots must also be worn in accordance with FPK
See Photos one and two below

The Health and Safety Executive (HSE) refer to safety equipment that is worn as Personal Protective Equipment or PPE. This term covers all such equipment, including items such as ear defenders and safety glasses. You should regard FPK and FPK (Fire) as being two types of PPE that are particular to Bonaprene Products.

Photo 1: FPK Front view

Photo 2: FPK Side view

1A) Methaline Bis Ortho Chloro Aniline (MBOCA)

Mboca (pronounced Mocca) is a golden coloured solid at room temperature. When fresh it is in a granular form (similar in appearance and texture to instant coffee) and is purchased in cardboard kegs of either 50 or 60kg's. The granules are sealed in a black plastic liner bag within the keg.

Mboca is a suspected carcinogen (cancer forming agent). It is known that similar substances have been responsible for cases of bladder cancer. Mboca does not stay in the body long but it does accumulate in urine before being passed out. It is, therefore, considered that Mboca may also have the same effect. It is important to note that the biggest known cause of bladder cancer is smoking.

The primary means of entry into the body is through the skin but also via ingestion and inhalation.

Extensive testing by a company called A&M Belting in Northern Ireland demonstrated that finished components pose no risk of Mboca exposure. They also concluded that the extent to which Mboca is absorbed and retained in the body varies between individuals.

The UK limit for the amount of Mboca that may be detected during medical examination is:

5 nanomolecules of Mboca / milli-molecule of Creatine

This was lowered from **15** in about 2018 as processors became more adept at controlling exposure and hence absorption.

To be sure we set this figure at ZERO

Storage

Fresh solid Mboca should be kept in the kegs, which should remain sealed until ready for use in their designated area, securely on shelves at room temperature. The labels should always remain clearly visible.

Mboca that is to be used should be transferred to the hopper a whole keg at a time. Operatives who load the hopper must do so wearing full protective kit. Unprotected personnel must keep well away from the loading area. During loading, the Mboca extraction ports must be opened. Once loading is complete the hopper lid must be replaced, the extraction port closed and all spilled granules and dust must be cleaned up. It is preferable that this is done by vacuuming rather than sweeping.

Using and Processing

Whenever using Mboca, full protective kit must be worn without exception. This rule applies even when working indirectly with the material, such as maintaining potentially contaminated equipment. It is important that chemical barrier gloves be worn rather than just heat resistant gloves such as leather and cotton liners. Rubber 'marigold' type gloves, PVC gloves or latex powdered gloves are the main form of chemical barrier gloves suggested

Mboca is processed at 105°C ~ 120°C so care must also be taken to avoid the possibility of burns by having no exposed skin when handling and always keeping your face, especially your eyes, protected. Do not overheat it. At temperatures above 150°C toxic gases are given off.

Never touch the material in either its dry or molten form with bare hands. Always remove

gloves before touching other parts of your body such as scratching your face, rubbing your eyes or raising your visor. Always wash your hands thoroughly before going to the toilet and especially thoroughly before eating or smoking. Never wear your overalls in the canteen, always change out of them before you go home and avoid touching contaminated clothing.

Many operatives who believe that they are being careful with Mboca and following all of the precautions mentioned so far still have the material detected in their urine following routine medical screening. This often comes about via secondary contamination or contamination arising from contamination! Mboca can transfer from, say, contaminated gloves to visor linings, or from desk tops to safety glasses. Try to keep items separate and be aware of this problem

The aim of all these precautions is to prevent a possibly carcinogenic chemical that can be absorbed through the skin coming into contact with exposed skin or being ingested through the mouth or nose. Be safe and apply these rules to all the chemicals you use.

Spillage

Spilled Mboca must be cleaned up immediately and thoroughly. The operative doing the cleaning should wear full protective kit (FPK) and the ideal method is by vacuuming into a sealed container.

Whenever you encounter spilled Mboca, clean it up immediately regardless of whether or not you are responsible for it. Allow liquid Mboca to freeze before cleaning it up. If you are unable to clean it up there and then, inform the Casting Shop Supervisor of its presence. If you find Mboca that is not spilt but is not in its correct place, as outlined under “Storage” inform the Casting Shop Supervisor.

Fire

Whilst Mboca is not a particularly flammable material, it has a flash point in excess of 250°C, it will burn and when it does it gives off toxic gases. It can be extinguished using all kinds of fire extinguishers used in the factory including water spray.

When attempting to extinguish burning Mboca, wear a breathing helmet, leather gloves, cotton overalls and leather boots. Do NOT wear Nylon overalls or rubber gloves.

In all cases of fire, the FIRST action is to sound the fire alarm alerting others to the danger and ensuring evacuation of the building NO MATTER HOW SMALL THE FIRE.

First Aid

Eyes - Rinse copiously with eye wash (Make sure that you know where the eye-wash stations are located.) If eyewash is not available then clean water may be used.

Skin contact (dry) - Remove and clean or dispose of all contaminated clothing. Wash the affected areas and beyond with soap and water.

Skin contact (molten) - Rinse copiously with any source of clean water Using water to cool the material and skin as quickly as possible is the priority here to prevent further burning.

Remember that the closest source of water may be an eyewash station or a drinking fountain.

Inhalation - Move the casualty into fresh air (Outside would be best so long as it is not too cold or warm and it is safe to move the casualty) then transfer to hospital.

Ingestion - If conscious, induce vomiting then transfer to hospital.

Notice that, here, vomiting *should* be induced unlike most of the other chemicals where you should not do this. This is because Mboca causes less harm to the throat than it would if left in the stomach as a poison.

End of extract 1

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We operate a zero-contact system both in policy and in terms of mechanical handling. The Mboca is stored in its packaging (Sealed polyethene bags inside sealed cardboard kegs with steel reinforcement rings) until immediately required. The unopened keg is placed in a holding frame in a man-cage FLT attachment which is then raised to a hopper. The fully protectively kitted operative then opens the three-sided extraction port, removes the lid of the keg and pours the entire content into the hopper. To transfer the Mboca into the melting vat a horizontal guillotine style valve with an extended handle is used. The vat is located in a fume cupboard enclosed on all but the working side. The LEV ensures that all fumes are pulled into the cupboard, ensuring a constant air flow *away* from the operator. To transfer the, now molten, Mboca to a mixing container ball valve, again with an extended handle does the job. The whole system is gravity fed and all need to touch the substance even with gloved hands is eliminated. See Photo's 2. 3 and below.

Control testing and internal environmental contamination

It should be ensured that those outside of the casting department are not at risk of secondary contamination. To this end, with each ecological testing session a number of randomly selected non casting staff are also tested for any indication of Mboca in the urine. These results should always be 'non detected'

Furthermore, surface testing is carried out. Amine swipe tests are performed around the factory and offices. These too are expected to come out negative. This is achieved through general good housekeeping, inculcation of the dangers and safety procedures, an extensive and powerful LEV system and supervisory vigilance. See Photos 3, 4 & 5 below.

Photo 3: E1 the largest of five powerful extraction fans

Photo 4: Fume cupboards showing vat enclosed in fume cupboard with gravity hopper above

Photo 5: extraction ports to each of the degassing vessels

Downstream operatives

Nearly every part produced is handled by downstream operatives; be they trimmers, stockmen or packers. It is important to ensure that they are not exposed to and possibly contaminated by products cast using Mboca curative. This is done in three ways:

- As mentioned above amine surface swipe tests are carried out to ensure that dust is not transferred to other departments
- Ecological testing is carried out as mentioned above
- Again, as already mentioned; A&M Belting in Northern Ireland carried out extensive testing to demonstrate that no Mboca is released by finished cast products

To reinforce this, it can be confidently asserted that Mboca, once processed, ceases to exist. This is demonstrated by the chemical formulations and reactions shown below

When Mboca is used as the curative to make solid polyurethane elastomers, the amine groups on the Mboca molecule react with the NCO groups of the isocyanate in a urea reaction:

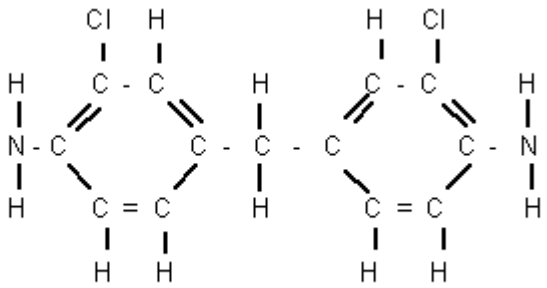


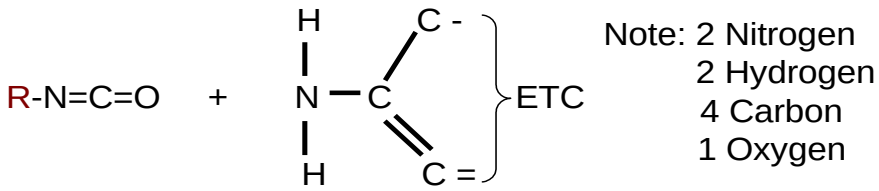
Figure 1: The Mboca molecule showing the terminal (NH2) amine groups.

Below is a second extract from the aforementioned training program which shows the process by which Mboca ceases to exist and becomes merely a segment of the polyurethane molecule

Extract 2: From training program:

The **UREA** reaction

Fig 3.19



Becomes…

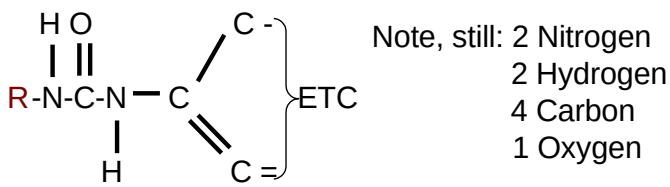
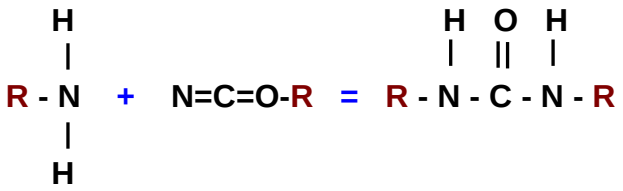


Fig. 3.20

You can see that in both Figures 3.19 and 3.20 we have the same atoms but arranged differently.

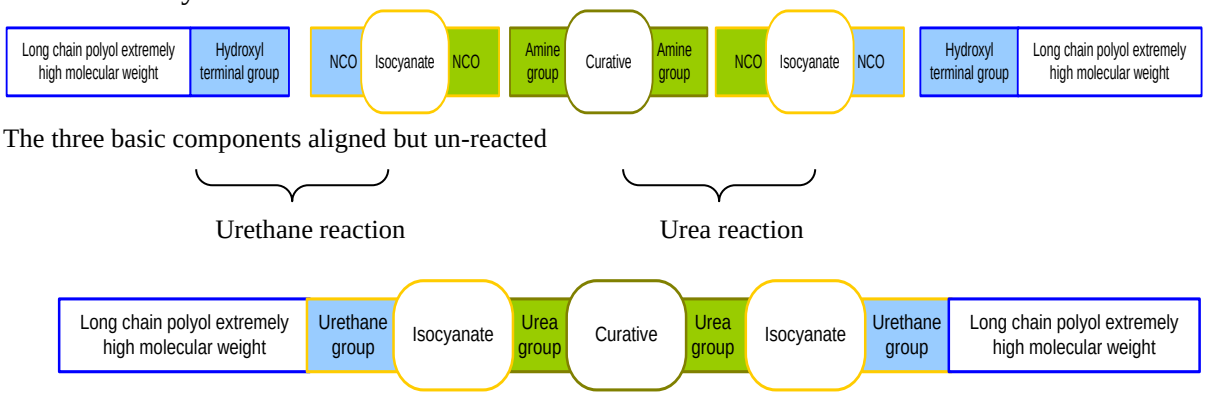
This is called a urea reaction. If you look at Figure 3.15 you will see that on each end of the Mboca molecule there is an NH_2 group of atoms. This is called an AMINE group. When amine reacts with Isocyanate the molecule that is formed is called UREA.



Amine group + Isocyanate = Urea group

What is happening here is that the NCO molecule within the prepolymer molecule is slightly unstable and is looking for what are known as active hydrogen atoms so it can react with them. It finds them in the amine group on each side of the MBOCA molecule and so reacts with it.

So in summary:



The components have now reacted to form a PU molecule. NCO has reacted with the hydroxyl groups to form urethane groups and it is the multitude of these that give the material its name.
Fig. 3.21

End of Extract 2

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As an excess of prepolymer is typically used, Mboca is fully consumed by the reaction.

Thus, it is demonstrated that Mboca can be considered as an intermediate material / substance.

Reviewing the Courbis Synthese application reveals their twelve sites to be operating in very similar ways to Bonaprene

Extract 3: From Courbis Synthese Application 2/8/21 9.0.2.4 P29 Consumers:

Exposure assessment is not applicable as there is no consumer-related uses of Mboca. Mboca is fully reacted with the prepolymer and there is no free MOCA present in the PU articles. Test data on representative samples of PU products manufactured at all 12 sites confirm that the amount of free MOCA is below less than 0.1 % (w/w) or so low that they were non-detectable.

End of Extract 3

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Wider considerations for the protection of the natural environment.

As all of this expensive substance is consumed in the manufacturing process there should be no release into the wider environment. Bonaprene takes its responsibilities to the environment very seriously. All hazardous materials are disposed of via registered hazard waste disposal companies and records are kept. All staff are trained and inculcated in the need to ensure that there is no chemical contamination of the ground or water courses. All new staff sign a letter (See Extract 4 below) on joining the company to show that they understand this. This is especially the case as Bonaprene is located in the river Dee catchment are. See Photos 6 & 7 below:

Photo 6: Sign reminding staff of the need for care when disposing of materials

Photo 7: covered hazardous waste storage bund. Please note that the drum to the left is brand new and empty

Extract 4: Waste disposal letter

Bonaprene headed paper here

PE017. Issue 3.

17/5/202X

Dear XXX,

Bonaprene Products is situated within the Dee Catchment Area; this means that the Environment Agency monitors closely the discharge of any chemicals into the water course. Any illegal discharge carries severe penalties.

Bonaprene Products operates a zero-discharge policy. This means that we are to allow no chemicals to be discharged into the ground or drains. All waste chemicals are to be stored in drums within the bund located at the back of the factory.

Small metal containers of five litres capacity or less such as paint or pigment tins must be disposed of in a dedicated 205 litre steel drum. This drum will be stored within the factory until full. Do not dispose of such containers in the general waste or the waste steel skip.

Any employee who deliberately fails to comply with this will be immediately placed in the three-stage dismissal procedure.

If you are unsure about how to dispose of any substance then please ask me for guidance. If you have an accidental spillage of any kind then please inform me immediately.

Yours sincerely,

Richard Mills.
Production Director.

I have, received, read and understood this letter.

……..Date……

End of Extract 4

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For further information on the applicant's processing methods, safety procedures and limitations on use see the risk assessment RA23 Issue 12 on page five

Analysis of Alternatives and Substitution

The following section provides an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant.

Some twenty years ago the applicant took the decision to move away from Mboca as the principal curative as far as possible. Initially great strides were made as the 'low hanging fruit was harvested'. As time has passed the benefits have become ever more marginal whilst the costs have risen considerably. Never-the-less the applicant has gone from using Mboca for some 97% of production in 2001 to it being used on only 6% in 2021. Mboca itself only constitutes some 2% of resin raw material purchases in that year.

Such a large shift downwards in Mboca consumption was achieved by a fundamental material *system* change taking place. The applicant went from using Mboca cured Tdi (Toluene di-isocyanate) to Quasi Mdi (Diphenol Methane Di-isocyanate) Polyester. Whilst in many cases different types of PU can be readily substituted, the fact that changing away form Mboca forced an entire *system* change meant that in more specific applications direct substitution was not possible. Where substitution may still be possible it is extremely difficult to determine. These difficulties are covered in detail later on in this section 'The Process of Substitution.' Meanwhile; the following Table 1 below shows the list of 'systems' that are available and the limitations on their applications. Table 2 shows the possible direct Mboca alternatives that are compatible with Tdi prepolymers but are considered unsuitable for the applicant and the reasons why.

Material Type.	Strengths.	Weakness'
Tdi Polyether cured with Mboca.	• Hot & wet environnements. • Dynamic performance. Heavily loaded rollers that are expected to rotate & carry large weights need a PU that has good 'dynamic performance.' • Low viscosity makes melting down, mixing and degassing easier. • Mboca disperses readily into the mix. • Though PU's are generally poor at resisting high temperatures these are better than most.	• Resistance to cutting or tearing is poor. • They are not particularly poor at resisting chemical attack by solvents and oils but polyesters are better. • Limited hardness range. • Suspected carcinogenic curative • High processing temperatures
Tdi Polyester cured with Mboca.	• Resistance to cutting or tearing. • Resistance to abrasion. This is very useful for components that are subjected to a lot of wear such as scraper blades.	• High viscosity makes melting down, mixing and degassing difficult. Prone to voids in the product • Hot wet environments. Even in

Material Type.	Strengths.	Weakness'
	• Good resistance to solvent attack. Rollers that are used to apply paints are often made to swell up by the solvent in the paint and these materials are good at resisting that. • Mboca disperses readily into the mix.	only slightly elevated temperatures with high natural humidity, such as the Far East, polyesters will begin to break down. • Limited hardness range. • Carcinogenic curative • High processing temperatures
Tdi Polyester cured with TMP.	• Low hardness's. This prepolymer / curative combination is one of the few ways to achieve hardness's below 55°A. • They are easy to process because they have a very long pot life (However, see de-moulding under weaknesses.) • Good resistance to solvent attack.	• Dynamic performance. • Resistance to abrasion. • Hot wet environments. It's a polyester! • Poor cut and tear resistance especially when hot. (They are very prone to tearing if they are de-moulded while still hot.) • Maximum hardness is 55°A
Quasi Mdi Polyether	• Resistance to abrasion. • Hot wet environments. • In both these areas straight Mdi systems are even better than Tdi systems. • Wide hardness range • Very good for machine dispensing. • Low process temperatures. • Non-carcinogenic curatives.	• Cost. • Hand processing involves laborious preparation. • Poor dynamic performance a key aspect for PU being specified
Quasi Mdi Polyester	• Good abrasion, cut resistance. • Cost. • Wide hardness range. • Very good for machine dispensing. • Low process temperatures • Non-carcinogenic curatives.	• Hand processing involves laborious preparation. • Prone to moisture degradation. • Hot wet environments. It's a polyester! • Poor dynamic performance a key aspect for PU being specified

Table 1 Applications of PU systems

Note that good dynamic performance is the principle selling point for PU elastomers and so is the key reason that it is specified by design engineers. None of the other systems, all of which are used by the applicant, can match the performance of Mboca cured Tdi polyether

Table 2, below, shows the failings of tested direct Mboca substitutes. Please note the following:

- The cost information is not up to date (As there have been massive increases over the past six to eight months) but the purpose is to show relativity to Mboca

- The higher the weight in column three the more curative has to be used and so the higher the end cost

Curative	Cost	Weight per 100g of prepolymer	Failings
Mboca	£4.15	12.8	Extensive, thorough safety procedures must be applied Authorisation is required
E300 Ethacure	£8.10	10.2	Lower abrasion resistance Degradation under UV (Unsuitable for outdoor applications) Prone to oxidation Lower viscosity causing processing / quality difficulties High cost
MCDEA	£22.00	18.1	Short pot-life causing processing / quality difficulties Very high cost
Polacue 740M / Versalink 740M	£15.00	15	Will not process with polyesters Strong brown colour makes it unsuitable in aesthetic applications High cost
Addolink 1604 / Baytec 1604	£15.00	11.5	Long de-mould time causing processing / quality difficulties Susceptible to hydrolysis High cost

Table 2 Failings of direct Mboca substitutes

The Process of Substitution

The applicant is a small company turning over some £4m with a staff of about fifty employees. All development has to be done within the production environment and so incurs the opportunity cost of lost output as well as the direct cost associate with development and experimentation. Though the following sub-section is based on a generalisation of the PU processing industry it is highly applicable to the applicant

The manufacture of cast polyurethane is a multi-step process, which starts by heating / melting, degassing and metering the prepolymer and the chain extender (e.g. Mboca). They are then mixed thoroughly together. The prepolymer and chain extender react together to form a liquid polyurethane reaction mixture that is then poured to a pre-heated mould. The filled mould is then placed into an oven for curing. Once the polyurethane has built enough strength, the mould is taken out of the oven and the PU part is removed from the mould. The PU part is then returned to the oven for post-cure. After post-cure, the PU part may be machined to achieve a specific finish.

The PU parts produced by PU processors need to meet strict technical requirements. These are set by customers and / or required by the end-use. The key technical requirements for the products covered by this

Applications include

- Abrasion resistance
- Ageing resistance
- Aggressive chemical resistance
- Coefficient of friction
- Compression set
- Cut resistance
- Durability
- Dynamic properties
- Elasticity
- Elongation at break
- Fatigue
- Heat resistance
- High final physical mechanical properties
- Hysteresis
- Load bearing capacity
- Mechanical strength
- Oil and grease resistance
- Ozone resistance
- Rebound resilience
- Sea water resistance
- Non-stick surface free of defects
- Temperature resistance
- Tensile strength
- UV resistance
- Wear resistance
- Weather resistance

To produce polyurethane, PU processors use commodity chemicals and process technologies that they may also purchase from their suppliers of commodity chemicals. Thus, the chemicals they use need to be commercially available at the purities required, in the tonnages needed and compatible with processing technology that is also commercially available (i.e. the casting machines). The

manufacture or supply of commodity chemicals is the domain of chemical companies (i.e. companies that would normally be referred to as “alternatives providers” using the terminology of the authorisation process or “system providers” using the terminology of the PU sector). PU processors are not in the business of chemical manufacture and will therefore always need to rely on their system providers for their raw materials. The system providers will react to the market and develop new systems based on what they can sell to their customers. System providers also may offer the machines and other process technology for PU manufacture with their specific trademarked systems. This means that system providers and PU processors always work in close collaboration on PU systems.

PU processors will generally have many formulations they have optimised and qualified to produce PUs with specific properties. The versatility of the TDI/Mboca system is that one system will have many formulation options meaning that the machines and processing equipment can be used to produce PUs with a range of properties. On a practical level, this means that they need to identify alternatives for each formulation.

PU processors have conducted extensive R&D work both before and after the sunset date of Mboca (22 November 2017). For years, the PU processors have worked in close collaboration with system providers to find a suitable alternative to Mboca. This ongoing collaboration takes the form of discussions between both parties, where the PU processors provide the key requirements for their PU products in terms of technical performance but also for the processing characteristics of the system.

Wherever it was possible, the PU processors have substituted Mboca. Such cases include PU products that have less demanding technical requirements. Thus, the present authorisation application only covers PU products for which a suitable alternative was not found. At time of submission of this application, none of the tested alternatives are suitable to replace Mboca in the products covered by this application.

It is currently uncertain when a Mboca-free PU system that combines the required processability, performance and cost profile. Even more now that the prices of the Mboca free PU systems are currently soaring. In contrast, the PU market is constantly pushing for lower pricing. Thus, it could take several years before a suitable alternative is available to the PU processors covered by this authorisation application.

A review period of seven years is requested by the applicants. Several factors were taken into account when deriving the review period including the current lack of suitable alternatives to replace Mboca, the high competitivity of the cast PU market, the current lack of restrictions on imports of Mboca-based PU products and the time needed to reformulate the current Mboca formulations

Factors affecting substitution

The substitution of Mboca is made complex by several factors. Some arise from the current state of the cast polyurethane market and the different motivations of the various actors while others arise from the very unique properties of Mboca. First, the TDI / Mboca system has a long history of successful use. Mboca cured PU has gained strong customer confidence due to its excellent durability and technical performances while its price is very competitive. It is thus not surprising that the PU processors’ customers (the end-users) seek the guaranteed quality of Mboca cured PU. In fact, the end-users have absolutely no driver to transfer to non-Mboca based products. The alternatives do not yield products with the same quality to cost ratio. In addition, the newly developed alternative PU products are relatively untested compared to the Mboca based products, which benefit from a very

long track record. The transition would therefore, require the end-users to take a risk, which may cost them in production downtime and repairs.

The situation would be easier if the PU processors and their customers would have a common goal of finding alternatives to Mboca-based products. Unfortunately, this is not the case as the end-users are solely concerned about product price, durability and technical performance. For the PU processors, there is a very real risk that their customers prefer to continue using the TDI / Mboca-products they are familiar with instead of using the relatively untested Mboca-free products.

The Mboca-products manufactured outside of the EEA and UK that are placed on the UK market are the main contributors to this risk. As the Mboca content of fully cured PU products is well below the <0.1 % threshold, the non-EEA PU processors can freely continue to place their Mboca-products on the UK market. Considering that Mboca is still the most used chain extender in the production of cast polyurethane outside of the EEA (Mboca represent approx. 70 % of the chain extender sales in North America and Australia and approx. 85 % of the sales in Asia based on the Amec report (1) and a recent market report (2) the threat to the applicants is very real. Their customers may leave them for a non-UK or even non-EEA PU processor at any time

This puts the applicants in a very vulnerable situation and also sets certain requirements for the alternatives. A suitable alternative is one that allows the PU processors to remain competitive, both in terms of product performance and price. In practice, it means that the alternative PU products must be at least as performant as TDI / Mboca-based products for the same price or performing better for a higher price. The contrary would make the UK PU processors more expensive and of lower quality, which could lead to the slow disappearance of the cast PU industry in the UK. In this case, the UK end users would need to rely solely on non-EEA or UK PU processors for the purchase of their PU parts. This increases the risk for disruption in the supply chain and the load on the environment as the majority of PU parts would need to be shipped from Asia, North America or Australia.

TDI / Mboca formulations are known for their versatility and ability to yield excellent all round PU properties. Different formulations of the same system are used to produce very different PU products for a variety of industry sectors. In addition, the long pot-life of TDI/MOCA formulations enables the production of both large and small PU parts with the same system. It is therefore, highly unlikely that a single alternative system can replace a single TDI/Mboca formulation. This is corroborated by the Amec report (1), where it is explained that MOCA does not have any “drop-in” replacement that would equal the cost-benefit profile of Mboca.

The importance of testing the alternative PU systems in the PU processors’ production lines is also be highlighted. Tests conducted at R&D scale can give an indication of the properties of the PU material but do not provide the full picture of how the PU system will work at industrial scale. For this reason, the system providers often send their specialists to assist the PU processors to conduct trials of new PU systems in their production lines.

1. *Comment 1161 submitted in the public consultation available on the ECHA website at https://echa.europa.eu/applications-for-authorisation-previous-consultations (application ID 0094-*

2. See Market research report on ”Polyurethane Elastomers Market 2021-2026” available at https://www.giiresearch.com/report/ina996450-polyurethane-elastomers-market.html?

List of actions and timetable with milestones

The following sub-section shows the laborious but necessary procedures for establishing the suitability of alternatives. The process involves four phases conducted in sequential manner and a continuous phase that is conducted in parallel. Each phase has a go/no go milestone with specific criteria that needs to be met before the substitution project can advance to the next phase.

Phase 0: Identification of alternatives

Phase 0 is the continuous phase. It is dedicated to the search for suitable alternatives to TDI / Mboca formulations and will continue until all Mboca has been substituted. Phase 0 breaks down as follows:

1. Analysing the products and customers concerned by the reformulation.

2. Analysing the conditions of end-use.

3. Defining the technical, economic and processability requirements for the formulation.

4. Collaborating closely with system providers through discussions between both parties, where the PU processors provide the key requirements for their PU products in terms of technical performance, costs and processing characteristics of the system.

Milestone: Phase 1 is started as soon as a potential alternative candidate has been identified. In parallel to working on phase 1, the PU processors will continue phase 0 in an aim to identify additional potential alternative candidates as there is no certainty that the identified alternative candidate will be suitable and feasible for them. The substitution work consists of trial and error and requires many iterations.

Phase 1: Formulation tests and R&D-scale testing

Once a potential alternative candidate has been identified, the formulation with the potential alternative can be developed and optimised. This step consists of a series of trial and error where the ratio of raw materials and of possible additives is optimised. R&D scale tests will be carried out between each iteration to gather preliminary test data on the mechanical and dynamic properties of the PU and the pot-life of the system. The results are then compared with the results obtained with the Mboca formulation and the requirements set in the previous phase for the PU processing and properties. The alternative provider may provide assistance with the steps described above.

If the preliminary test data is promising, the PU processor will conduct an economic appraisal on the new PU formulation.

Milestone: If the new Mboca-free formulation is suitable in terms of costs and the technical properties of the PU are within acceptable range, the project will move to phase 2. Otherwise, the new Mboca-free formulation will be abandoned and a new potential alternative candidate will need to be identified (phase 0).

Phase 2: Upscaling tests and processing trials

In phase 2, the formulation is tested at industrial scale at the PU processor's site. During the upscaling to industrial scale, several issues may arise due to the larger batch volumes required, such as problems with the reactivity of the system, narrower hardness range of the material, PU shrinkage and cracks in the PU. The alternative provider generally provides technical support with the upscaling by sending a specialist to the PU providers facilities to test the new formulation on the PU production line. The tests consist of a series of trial and error where the process parameters are optimised, and the

resulting PU is tested in laboratory (In the case of the applicant this has to be sub-contracted out, adding to the time and cost) setting to determine mechanical and dynamic properties of the PU. The need for adaptations of the PU production line and modifications to the casting machine will be assessed and discussed with the specialist from the alternative provider.

During this phase, prototypes of the PU products are cast with the new formulation. The PU processors also assess whether their existing moulds need to be redesigned. As each PU system has its own shrinkage profile, it is expected that the PU processors will need to redesign all of their moulds when switching to an alternative. To this end, the PU processors need to make new technical drawings for the moulds and order them as custom-made pieces from an external provider.

The scrap rate of the system is also assessed during this stage. It consists of conducting a visual inspection of the PU products casted and calculating the number of unacceptable products against the number of products produced. Unacceptable PU products are, for instance, products with faults, air bubbles, cracks or other types of defects.

Milestone: The project will advance to the next phase if the PU produced with the new formulation fulfils the technical requirements, the new or adapted production process is reliable and technical specifications can be set for the PU products with an acceptable scrap rate and the new moulds have been received. The PU products made with the new formulation need as a minimum to be as performant as the original Mboca products and with comparable production costs. Otherwise, the PU processors will not have a market.

If, despite the many trials to optimise the formulation at industrial scale and the processing parameters, the technical or economic requirements (e.g. scrap rate) cannot be achieved with the new formulation, the PU processors will first assess whether their casting machine needs to be (further) modified. In case this is unsuccessful, the project will return to phase 0.

Phase 3: Customer trials

The tests conducted in small scale settings on the prototypes in the previous phase give an indication of the technical performance of the PU products but it cannot fully simulate the stress and conditions the PU will undergo during end-use. For this reason, tests carried out with the customers are needed.

In this phase, the PU processors contact a given number of customers in an aim to convince them to test the products made with the new Mboca-free formulation. It is a complex task as the trials may cause downtime in the customers' production lines and there also risks of malfunctions as the new PU product is untested in real-life settings. This is one of the reasons why the new PU product must at least equal the Mboca-based product in terms of technical performance and price as the customers have no interest in losing time and money testing a lower quality or more expensive product.

Where the customer agrees to test the products, the PU processors will cast prototypes with the new formulation and deliver them to the customer. A report will be drawn with the observations and feedback given by the customer. Any adaptations the customer had to make to his process will also be recorded. All the received feedback will then be analysed and compared.

Customer trials are the most time-consuming activities after the identification of alternatives. Depending on the end-use, the customer trials may last from several months to years. This is to allow for the full assessment of the new material's durability and behaviour throughout the lifetime of the product.

Milestone: If the trials were successful, the project will progress to the next phase. If the performance of the new PU product was worse (e.g. lower durability, failure) than the Mboca PU, the project will return to Phase 0

Phase 4: Commercial agreement

For the last phase of the reformulation, the PU processors discuss with the customers concerned by the reformulation of signing a commercial agreement for the new non-Mboca based products. The outcome of this phase relies heavily on the customer and their willingness to buy the new product.

Once the commercial agreements have been signed, the PU processors need to update their production processes for the products concerned and relevant internal documentation (e.g. technical specification sheets, quality documentation for production, testing, safety, etc.).

Milestone: The customers sign commercial agreements for the new non-Mboca based products. MOCA is replaced with an alternative in the production of this particular formulation. If the customers are not satisfied with the new products and refuse to buy them, the project will return to phase 0.

The breakdown of the durations for one reformulation is as follows: -

Phase 1: 2-6 months –

Phase 2: 6-12 months –

Phase 3: 8-16 months –

Phase 4: 2-6 months

As outlined above the phases 1 ~ 4 are conducted in a sequential manner meaning that the next phase begins only when the milestone of the current phase has been fulfilled.

Conclusions

This section documents the main factors affecting the substitution of Mboca, the actions required to reformulate a Mboca-based formulation, timelines for the substitution of Mboca and information on the monitoring systems in place.

As outlined in the section, the substitution of Mboca is still years away. There are several factors affecting the substitution. The high competitiveness of the cast PU market means it is nearly impossible for the PU processors to reflect the increase in production costs into their product price. This is also the result from the lack of restriction on imports of Mboca based PU products to the UK as well as from the continued use of Mboca outside of the UK &EEA, which, needs to be noted, is still the most used chain extender in cast PU production in North America, Asia and Australia. This hampers the PU processors' ability to substitute and puts them in a vulnerable position where their customers may leave them for a PU processor based outside of the UK or EEA.

The customers, who are the end-users of the PU products, drive the substitution. They are solely interested in product performance and price. They base their purchase decisions on these factors and there is a very real risk they will prefer to continue using Mboca -based products if the alternative products cannot achieve the same price / quality ratio of Mboca based products. This is a particularly complex task at the moment as the price of non Mboca based systems are currently soaring. For these reasons, the companies need time to implement affordable substitutes to Mboca that does not render them non-competitive and therefore out of the market.

Socio-Economic Analysis

It is not possible for a company the size of the applicant to provide a complex, in depth analysis with sensitivity modulation and weighting etcetera. However, this does not mean that there is no need for any such analysis and I would refer the reader to the application made by Courbis Synthese on behalf of a consortium of 12 European Companies to EU-REACH. ID 0246-01 Adopted opinions and previous consultations on applications for authorisation - ECHA (europa.eu). Studying this report reveals that the twelve companies all operate in a very similar way to the applicant (Bonaprene Products Limited.) The relevant section of this report provides an excellent general socio-economic analysis for such companies.

Specifically, to the applicant it is estimated that four or even six jobs would be at risk should they no longer be allowed to process Mboca. Two in Engineering, two in Casting and one in Finishing & Despatch. Though the total numbers may seem low on a national scale, they would represent some 20% of the shop-floor workforce. Considering that the company has demonstrated continuously for the last twenty or more years that it can process the substance safely, the economics to health ratio would, in fact, be high. Three of the jobs would be semi-skilled and two skilled; all well paid in a geographic area which is not particularly wealthy. (Wrexham, North Wales)

One of the major uses of the substance by the applicant is in the manufacture and refurbishment of industrial rollers for steel mills. This application, above all else, demands the use of Mboca as the curative. The physical properties, which cannot be replicated by alternative curatives or 'systems' are precisely those required here. There is also a multiplier effect in this area of the business; many customers demand a one-stop-shop contract from their suppliers. The applicant is expected to supply all rollers in the contract. Not being able to do so could mean the entire contract being lost and the employment effects could be doubled.

The UK steel industry already struggles with low-cost foreign competition. Being forced to source their rollers from outside of the UK or EU would be yet another incentive to move production to the Far East. Again, there is a multiplier effect. Far Eastern steel mills would be able to buy the higher quality Mboca cured rollers on, local, short lead times. UK steel mills would have to either accept lower quality rollers they would have to hold higher stocks of spares due to the long shipping lead times.

The second largest use of Mboca by the applicant is the production of hydro-cyclones for the paper industry. The applicant is the only producer of such items in the UK and they would simply be imported from the USA. Though on a smaller scale all of the arguments applicable to the steel mill rollers situation would apply here

A high value and critical product of the applicants' is polyurethane isostatic pressing bags. These, in turn, are used to make ultrafine particulate filters. These filters are the core feature on medical ventilators. As the reader can imagine demand for these has been very high over the past couple of years. Though is has fallen back in the past six months it is still expected to be at a higher level than pre-COVID times. For this product no other curative has proved capable of serving the purpose.

In conclusion; though the total number of jobs at risk seems low each one of them is an individual whose life will be detrimentally affected. Some 20% of the shop floor work force will be under threat of redundancy. These are well paid manufacturing jobs in an area that needs them. On the other hand, due to the careful, responsible approach of the company and the good house-keeping and personal hygiene of the staff the risks to heath are extremely low.

Conclusion

It is requested that authorisation be given for applicant company to continue using Mboca (Methylene Bis Ortho Chloro anilene for the next seven years under Article 62 of UK REACH Regulation (EC) No 1907/2006.

This request is made on the following basis; The applicant has:

- Demonstrated that it can process Mboca safely on a long-term on-going basis
- Steadily reduced its dependence on and consumption of the substance and will continue to strive to do so
- Total consumption in 2002 was 60 tonnes of all types. Despite this rising to some 130 tonnes in 2021 Mboca declined from four tonnes to 3.2 (6.6% declining to 2.4%)
- Through continuous effort achieved some 94 ~ 96% of all production being moved away from Mboca based systems
- Shown that, though this means that only 4 ~ 6% of production relies on Mboca, this legacy production is a critical part of the business
- Demonstrated the will and desire to continue to search for alternatives to the substance; in terms of both direct substitution and alternative systems
- Demonstrated that the socio-economic benefits are in favour of authorisation being given.
- Written and applied an NVQ III equivalent, NOCN accredited training programme that teaches in both theory and practice the dangers associated with Mboca and how it should safely be handled