

Our company manufactures small parts of less than ten kilograms, using cast elastomers. MOCA (Cas No. 101-14-4) is the curative used to form the majority of the polymers, present in the merchandise. The facility could be described as a specialist and a generalist moulder. A large number of products are provided for Original Equipment Manufacturers (OEM's) of stipulated sizes, interpreted as generalist processing. In combination, high volumes of smaller orders are supplied to a wide range of customers involved in different industries, referenced as specialist manufacturing. Approximately three hundred and fifty moulds, are available, variations can be attempted with dissimilar inserts/compounds.

Parts made, in terms of generalist and specialist handling, are finished to strict quality standards. The MOCA curing material, can flow around the inserts and fill the mould cavities, without incurring voids, air bubbles, cracks, spaces, or visible striations. The rheology of the standard compound is suited to the technique, less than five percent of parts formed, are rejected.

Since 1994, MOCA replacement work has been ongoing at this factory. Through the earlier phases, manual casting was used to make articles for evaluation. Physical performance, processing difficulties, and economic viability of the alternatives, were limiting factors. From 2004, low pressure dispensing equipment was utilised for more in depth experiments/tests. During the past twelve years, ten separate systems, both MDI and TDI have been attempted, via automated mixing machinery. Hundreds of prototypes have been made across the size/insert range. To date, no complete solution has been discovered. In general, the waste incurred has been too high for financial feasibility. To summarise, the flow properties of the MDI's have not been totally suitable. Voids, bubbles, poor shape replication and striations have been, so far, unresolved, regardless of compound/moulding parameter adjustments. The optimum MDI test system has shown >25% reject items, throughout the mould possibilities. TDI alternatives showed cracking in the finished objects, for a series of ten on the same shape, under controlled conditions, fissures were observed in at least 20% of the forms. It was therefore not viable to conduct larger scale assessments.

The substitutes tried, have been suggested by five suppliers, our firm does not have the resources, or the know how to make raw materials. In the recent twelve year time frame, several external technical experts have been on site, for numerous trials, to aid us with this effort. In parallel, to the dispenser experiments, separate samples have been obtained from four additional companies, for manual mixing tests, in our laboratory, and on the factory floor. Similar issues to those, outlined above, were encountered.

The potential for exposure to MOCA is low, due to the risk management measures on site. MOCA, is introduced to the plant in a sealed bag, in a cardboard drum. To process it, the chemical is transferred to a sealed hopper, with a circular opening similar in diameter to that of the open cardboard container. A rubber seal surrounds the orifice, ensuring a tight fit. After the drum has been attached to the side of the hopper, the internal doors can be opened, with the aid of the viewing window at the front. The bag can be opened inside the closed chamber. Internal non detachable gloves, allow this step without opening the compartment. The gloves are EN374 approved, the operator also wears protective glasses EN166, a half mask EN140, with P3 particulate filters, in addition to gas/vapour filters, and overalls. Similar personal protective wear is used during calibration of the dispenser. To maintain the metering machine, the MOCA filters in the pressurised line of the mixer, are

cleaned periodically. For this stage a Tyvek suit is applied, in cooperation with a forced air respirator, incorporating a P3 filter. A full face shield EN166 is part of the apparatus; gloves, EN374, are also worn. The casting operatives wear protective clothing and gloves. Firm standard practice hygiene measures are in place, diamine contaminated protective articles/clothing, are disposed of as incinerator waste.

Local exhaust ventilation systems are in place at each forming machine, and at the automated dispensing unit.

Analysis of cured urethane from our products, by a global technology group, showed that the amount of unreacted MOCA was well below 0.1% w/w. Biological monitoring of the workforce has shown that no worker has been above the threshold value for MOCA, 15  $\mu\text{mol}$  per mol of creatinine, in the past ten years. The steps the organisation has taken to implement mechanised blending, and the total phasing out of MOCA hand processing, have considerably influenced this record.

Our business fully supports the timelines and review period, requested in the authorisation application (12 years).