Polytopics

Quarter 2 - 2012

• MOCA • TDI • MDI •

Chemicals and Regulatory Requirements

by Donald P. Gallo, Esq., Reinhart Boerner Van Deuren s.c.

This article provides an overview of the chemical and regulatory basics pertaining to three highly regulated chemicals -- MOCA, TDI and MDI -- and includes information about the agencies and organizations that make it their mission to ensure safe manufacture and use of chemicals. Additional information can be accessed via the links listed throughout this article.

CHEMICALS

4,4'-Methylenebis(2-Chloroaniline) ("MOCA"/"MBOCA") is used for curing resins. Mixing it with diisocyanate-based prepolymer resins produces resistant polyurethane products and the polyurethane prepolymers are used in the manufacture of castable urethane products, such as shock-absorption pads and conveyor belting. *IARC Monographs,* monographs.iarc.fr/ENG/Monographs/vol99/mono99-13.pdf (citations omitted). It is also used as a coating in chemical reactions to "set" glues, plastics, and adhesives, and additional products "include gears, gaskets, sport boots, roller skate wheels, shoe soles, rolls and belt drives in cameras, computers and copy machines, wheels and pulleys for escalators and elevators, components in home appliances, and various military applications." *ATSDR - Toxic Substances Portal,* http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=209. Occupational exposure occurs during production and use, with the most prevalent exposure route being dermal absorption, rather than inhalation or ingestion. *IARC Monographs,* monographs.iarc.fr/ENG/Monographs/vol99/mono99-13.pdf.

Toluene Diisocyanates ("TDI") is used for preparing polyurethane foams, elastomers and coatings. It is also used as a cross-linking agent for nylon-6 and as a hardener in polyurethane adhesives and finishes. "Polyurethane elastomers made from toluene diisocyanates are used in coated fabrics and clay-pipe seals. Polyurethane coatings made from toluene diisocyanates are used in floor finishes, wood finishes and sealers, and in coatings for aircraft, tank trucks, truck trailers and truck fleets." *IARC Monographs*, monographs.iarc.fr/ENG/Monographs/vol71/mono71-37.pdf (citations omitted). Occupational exposures occur during production of TDI and TDI-containing products as well as during product use. *Id.* (TDI is a respiratory irritant and sensitizer).

4,4-Methylenediphenyl Diisocyanate and Polymeric 4,4-Methylenediphenyl Diisocyanate ("MDI") is used to produce rigid polyurethane foams as well as paints, adhesives, weather-resistant sealing materials, footwear, particle board, and mould cores for the foundry industry. *IARC Monographs,* monographs.iarc.fr/ENG/Monographs/vol71/mono71-47.pdf (citations omitted). MDI irritates skin, eyes, and respiration. *Id.*

AGENCIES, ORGANIZATIONS, and CHEMICAL REQUIREMENTS

IARC. The International Agency for Research on Cancer (IARC) is part of the World Health Organization. "IARC's mission is to coordinate and conduct research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer prevention and control. The Agency is involved in both epidemiological and laboratory research and disseminates scientific information through publications, meetings, courses, and fellowships." *IARC - International Agency for Research on Cancer,* http://www.iarc.fr/. To further IARC's mission of promoting international collaboration on research for cancer prevention, IARC's founding members -- Germany, France, Italy, the United Kingdom and the United States -- have been joined by Australia, Austria, Belgium, Canada, Denmark, Finland, India, Ireland, Japan, Norway, the Netherlands, Republic of Korea, Russian Federation, Spain, Sweden, Switzerland and Turkey.[1] *IARC - International Agency for Research on Cancer - About IARC,* http://www.iarc.fr/en/about/index.php. IARC emphasizes explaining "the role of environmental and lifestyle risk factors and studying their interplay with genetic background in population-based studies and appropriate experimental models" and assists with cancer registries and monitoring of geographical variations and trends. *Id.* IARC has published monographs for MOCA, TDI, and MDI. *See IARC Monographs,* monographs.iarc.fr/ENG/Monographs/vol99/mono99-13.pdf; monographs.iarc.fr/ENG/Monographs/vol71/mono71-37.pdf; monographs.iarc.fr/ENG/Monographs/vol71/mono71-47.pdf.

ACGIH. The American Conference of Governmental Industrial Hygienists ("ACGIH") is a member-based organization that "encourage[s] the interchange of experience among industrial hygiene workers and to collect and make accessible such information and data as might be of aid to them in the proper fulfillment of their duties." *ACGIH - About,* http://www.acgih.org/About/history.htm. ACGIH's Threshold Limit Values ("TLV") for Chemical Substances Committee was established in 1941 to investigate, recommend, and annually review exposure limits for chemical substances. *Id.* (TLVs originally were known as Maximum Allowable Concentrations). The current TLV list includes 642 chemical substances and physical agents.[2] *Id.*

- **MOCA --** ACGIH assigned MOCA "an A2 notation, *suspected human carcinogen* (ACGIH, 2001). A TLV-TWA (threshold limit value–time weighted average) of 0.01 ppm (0.11 mg/m3) is recommended. A skin notation is assigned (*potentially significant contribution to the overall exposure by the cutaneous route*) in recognition of the consensus that skin absorption from direct contact is the major source of occupational exposure. Implementation of a urine-monitoring programme to ensure

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the effectiveness of dermal exposure control is encouraged." *IARC Monographs,* monographs.iarc.fr/ENG/Monographs/vol99/mono99-13.pdf. *See also Working Safely with Isocyanates and MOCA in Casting Operations* by Theodore J. Hogan, PhD, CIH and *MOCA Safe Use Guidelines for the Castable Polyurethane Industry* by Donald P. Gallo, Legal Counsel, and Theodore J. Hogan, Health and Safety Consultant.

- **TDI** -- ACGIH "recommended 0.036 mg/m3 as the 8-h time-weighted average threshold limit value for occupational exposures to 2,4-toluene diisocyanate in workplace air. Similar values have been used as standards or guidelines for 2,4- or 2,6-toluene diisocyanates in several countries. In some other countries, values ranging from 0.04 to 0.14 mg/m3 for mixed isomers have been used (International Labour Office, 1991)." *IARC Monographs*, monographs.iarc.fr/ENG/Monographs/vol71/mono71-37.pdf. *See also OSHA - Chemical Sampling Information,* http://www.osha.gov/dts/chemicalsampling/data/CH_272400.html (ACGIH TLV for TDI is: 0.005 ppm, 0.036 mg/m3 TWA; 0.02 ppm, 0.14 mg/m3 STEL; SEN; Appendix A4 - Not Classifiable as a Human Carcinogen). The proposed TLV-TWA is 0.001 ppm, inhalable fraction and vapor, with a TLV-STEL of 0.003 ppm inhalable fraction and vapor.[3] TDI also has a skin and SEN notation with an A3 carcinogenicity classification.

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- **MDI** -- ACGIH "recommended 0.051 mg/m3 as the threshold limit value for occupational exposure to 4,4-methylenediphenyl diisocyanate in the workplace air. Similar values have been used as standards or guidelines in many countries (International Labour Office, 1991). " *IARC Monographs*, monographs.iarc.fr/ENG/Monographs/vol71/mono71-47.pdf (citations omitted). *See also*

ATSDR. The Agency for Toxic Substances and Disease Registry ("ATSDR") "is a federal public health agency of the U.S. Department of Health and Human Services. ATSDR serves the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and diseases related to toxic substances." *ATSDR - Agency for Toxic Substances and Disease Registry,* http://www.atsdr.cdc.gov/. ATSDR publishes to minimal risk levels, which are estimates of "the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse, non-cancer health effects over a specified duration of exposure." *ATSDR - Toxic Substances Portal,* http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=209.

- **MOCA** -- ATSDR's minimal risk level for MOCA is 0.003 mg/kg/day. *ATSDR - Minimal Risk Levels (MRLs) for Hazardous Substances,* http://www.atsdr.cdc.gov/mrls/mrllist.asp#209tag. Moreover, ATSDR's most recent (2011) Priority List of Hazardous Substances That Will Be the Subject of Toxicological Profiles at Superfund Sites (the "Substance Priority List" or "SPL") ranks MOCA number 90.

NIOSH. The National Institute for Occupational Safety and Health ("NIOSH") is part of the Centers for Disease Control and Prevention ("CDC") in the Department of Health and Human Services and is responsible for conducting research and making recommendations for the prevention of work-related injury and illness. *Centers for Disease Control and Prevention - About NIOSH,* http://www.cdc.gov/niosh/about.html. NIOSH issues Criteria Documents, which review scientific and technical information on hazards, risks, and methods to identify and control hazards, and Special Hazard Reviews and Occupational Hazard Assessments, which assess safety and health problems and recommend control/monitoring methods. *Centers for Disease Control and Prevention - NIOSH Publications and Products,* http://www.cdc.gov/niosh/pubs/criteria_date_desc_nopubnumbers.html.

- **MOCA** -- NIOSH's recommended exposure limit ("REL") for MOCA is Ca TWA 0.003 mg/m3 [skin]. *Centers for Disease Control and Prevention - NIOSH Pocket Guide to Chemical Hazards,* http://www.cdc.gov/niosh/npg/npgd0411.html.
- **TDI** -- NIOSH lists TDI as immediately dangerous to life or health ("IDLH") at 2.5 ppm. *Centers for Disease Control and Prevention - NIOSH Pocket Guide to Chemical Hazards*, http://www.cdc.gov/niosh/npg/npgd0621.html; *ATSDR - Toxic Substances Portal - Toluene Diisocyanate,* http://www.atsdr.cdc.gov/mmg/mmg.asp?id=1139&tid=245.
- **MDI** --NIOSH's REL for methylene bisphenyl isocyanate is TWA 0.05 mg/m3 (0.005 ppm) C 0.2 mg/m3 (0.020 ppm)

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[10-minute]. NIOSH lists methylene bisphenyl isocyanate as IDLH at 75 mg/m3. *Centers for Disease Control and Prevention - NIOSH Pocket Guide to Chemical Hazards,* http://www.cdc.gov/niosh/npg/npgd0413.html.

NTP. The National Toxicology Program ("NTP") biennially publishes a congressionally mandated, science-based, public health report that identifies substances that may result in an increased cancer risk. *National Toxicology Program - About the Report on Carcinogens,* http://ntp.niehs.nih.gov/?objectid=03C9B512-ACF8-C1F3-ADBA53CAE848F635. This Report is cumulative and consists of both newly reviewed and previously listed substances: the most recent (twelfth) edition was published on June 10, 2011. *Id.*

- **MOCA** -- The NTP Report on Carcinogens lists MOCA as "reasonably anticipated to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in experimental animals. " *Report on Carcinogens, Twelfth Edition* (link at http://ntp.niehs.nih.gov/?objectid=03C9AF75-E1BF-FF40-DBA9EC0928DF8B15).
- **TDI** -- The NTP Report on Carcinogens lists Toluene diisocyanates as "reasonably anticipated to be human carcinogens based on sufficient evidence of carcinogenicity from studies in experimental animals." *Id.*

OSHA. The Occupational Safety and Health Administration ("OSHA") is part of the U.S. Department of Labor, and its mission is to ensure "safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance." *United States Department of Labor - About OSHA,* http://www.osha.gov/about.html. Employers are required to comply with all applicable OSHA standards and with OSHA's General Duty Clause, which requires employers to keep workplaces free of serious recognized hazards. *United States Department of Labor - OSHA Law and Regulations,* http://www.osha.gov/law-regs.html. "OSHA sets enforceable permissible exposure limits (PELs) to protect workers against the health effects of exposure to hazardous substances. PELs are regulatory limits on the amount or concentration of a substance in the air. They may also contain a skin designation. OSHA PELs are based on an 8-hour time weighted average (TWA) exposure. Permissible exposure limits (PELs) are addressed in specific standards for the general industry, shipyard employment, and the construction industry." *United States Department of Labor - Permissible Exposure Limits (PELs),* http://www.osha.gov/SLTC/pel/index.html. Most PELs are set forth in 29 C.F.R. § 1910.1000 TABLE Z-1.

- **MOCA --** The target concentration for MOCA is 0.2 mg/m3 (0.02 ppm): "0.02 ppm is the TLV of the American Conference of Governmental Industrial Hygienists. A skin notation is attached to the standard. The NIOSH recommended standard is 3 µg/m3 based on a time-weighted average. This value represents the detection limit for this method. (Ref. 5.7.)" *United States Department of Labor - 4,4'-METHYLENEBIS(O-CHLOROANILINE) [MOCA],* http://www.osha.gov/dts/sltc/methods/organic/org024/org024.html.
- **TDI and MDI --** "The current ceiling PEL for 2,4-toluene diisocyanate (2,4-TDI) and for methylene bisphenyl diisocyanate (MDI) is 0.02 ppm. This corresponds to 0.14 and 0.20 mg/m3 for 2,4-TDI and MDI respectively. The TWA PEL is 0.005 ppm for both diisocyanates. This corresponds to 0.035 mg/m3 for 2,4-TDI and 0.05 mg/m3 for MDI." *United States Department of Labor - DIISOCYANATES 2,4-TDI and MDI,* http://www.osha.gov/dts/sltc/methods/organic/org018/org018.html. *See also ATSDR - Toxic Substances Portal - Toluene Diisocyanate,* http://www.atsdr.cdc.gov/mmg/mmg.asp?id=1139&tid=245, 40 C.F.R. § 1910.1000 TABLE Z-1.

EPA. To fulfill its mission of protecting human health and the environment, the U.S. Environmental Protection Agency ("EPA"): develops and enforces regulations, gives grants, conducts laboratory studies of environmental problems, sponsors partnerships, and educates and informs the public. *United States Environmental Protection Agency - Our Mission and What We Do,* http://www.epa.gov/aboutepa/whatwedo.html.

- **MOCA --** On March 1, 2012, the EPA listed 83 chemicals or groups of chemicals for which it will conduct risk assessments. MOCA is listed as a known human carcinogen and received the highest hazard score (a "3"). Additionally, section 8(b) of the Toxic Substances Control Act ("TSCA") authorizes the EPA to list chemical substances manufactured or processed in the U.S., to obtain data regarding the substances, and the regulate the substances. MOCA is included on the TSCA list and requires a premanufacture notice. *See* Chemical Data Reporting rule at 40 CFR Part 711.

ECHA. The European Chemicals Agency's ("ECHA") mission statement states that "ECHA is the driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern." *European Chemicals Agency - Mission,* http://echa.europa.eu/web/guest/about-us/who-we-are/mission. REACH is a European Union regulation "adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals." *European Chemicals Agency - Regulations,* http://echa.europa.eu/web/guest/regulations. "Certain substances that may have serious and often irreversible effects on human health and the environment can be identified as Substances of Very High Concern (SVHCs). REACH aims at ensuring that the risks resulting from the use of SVHCs are controlled and that the substances be replaced where possible." *European Chemicals Agency - Substances of Very High Concern identification,* http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification.

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- **MOCA --** On January 8, 2011, MOCA was added to ECHA's Registry of submitted SVHC intentions (i.e., the ECHA Candidate List). "Producers and importers of articles [must] notify ECHA by 19 June 2012, if both of the following conditions apply: (i) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year and (ii) the substance is present in those articles above a concentration of 0.1 % weight by weight. There are exemptions from the notification obligation if the substance is already registered for the use or when exposure can be excluded." *European Chemicals Agency - ECHA updates the Candidate List with twenty new Substances of Very High Concern,* http://echa.europa.eu/web/guest/view-article/-/journal_content/a5533137-4976-4054-b8e8-da4a5b3dd623.

Endnotes

1. *IARC is not involved directly in implementation of control measures, nor does it conduct research on treatment or care of cancer patients. IARC - International Agency for Research on Cancer - About IARC, http://www.iarc.fr/en/about/index.php.*
2. *TLVs "are not standards. They are guidelines designed for use by industrial hygienists in making decisions regarding safe levels of exposure to various chemical substances and physical agents found in the workplace … [and] are based solely on health factors, there is no consideration given to economic or technical feasibility." ACGIH - TLV/BEI Resources, http://www.acgih.org/TLV/.*
3. *The Threshold Limit Value—Time–Weighted Average ("TLV–TWA") is the "TWA concentration for a conventional 8-hour workday and a 40-hour workweek, to which it is believed that nearly all workers may be repeatedly exposed, day after day, for a working lifetime without adverse effect." TLV & BEI Introduction on the Uses of TLVs and BEIs, http://www.acgih.org/Products/tlv_bei_intro.htm. The Threshold Limit Value—Short-Term Exposure Limit ("TLV–STEL") is a "15-minute TWA exposure that should not be exceeded at any time during a workday, even if the 8-hour TWA is within the TLV–TWA. The TLV–STEL is the concentration to which it is believed that workers can be exposed continuously for a short period of time without suffering from 1) irritation, 2) chronic or irreversible tissue damage, 3) dose-rate-dependent toxic effects, or 4) narcosis of sufficient degree to increase the likelihood of accidental injury, impaired self-rescue, or materially reduced work efficiency. The TLV–STEL will not necessarily protect against these effects if the daily TLV–TWA is exceeded." Id.*

2013 PMA Annual Meeting
Preliminary Schedule Overview
May 4-May 8, 2012 • Las Vegas, NV

Saturday, May 4, 2013

1:00 pm – 5:00 pm	Board & Committee Meetings

Sunday, May 5, 2013

8:00 am – 10:30 am	Committee Meetings
11:00 am – 5:00 pm	John Jarvis Golf Outing (lunch on course)
6:00 pm – 6:30 pm	New Member/Guest/First Timer Reception
6:30 pm – 11:00 pm	Welcoming Reception/ Activities

Monday, May 6, 2013

8:00 am – 8:30 am	Breakfast
8:00 am – 10:00 am	Spouse Gathering
8:30 am – 10:30 am	Keynote Speaker
10:30 am – 11:30 am	Panel Presentation following Keynote
11:30 am – 12:30 pm	Lunch
1:00 pm – 4:30 pm	Technical Paper Presentations
Open Evening	

Tuesday, May 7, 2013

8:00 am – 8:30 am	Breakfast
8:00 am – 10:00 am	Spouse Gathering
8:30 am – 10:30 pm	Keynote Speaker
10:30 am – 11:30 am	Regulatory Affairs Update
11:30 am – 12:30 am	Annual Meeting over Lunch
1:00 pm – 2:00 pm	Past President's Meeting
1:00 pm – 5:00 pm	Supplier Showcase
6:00 pm – 7:00 pm	Reception
7:00 pm – 9:00 pm	Awards Banquet

Wednesday, May 8, 2013

9:00 am – 11:00 am	Board & Committee Meetings

Subject to Change