Toluene Diisocyanate (TDI) And Related Compounds Action Plan [RIN 2070-ZA14]

I. Overview

This Action Plan addresses the use of toluene diisocyanate (TDI) and related compounds (See Appendix 1) in products that may result in consumer and general population exposures, particularly in or around buildings, including homes and schools. Diisocyanates are well known dermal and inhalation sensitizers in the workplace and have been documented to cause asthma, lung damage, and in severe cases, fatal reactions. This Action Plan focuses on the potential health effects that may result from exposures to the consumer or self-employed worker while using products containing uncured (unreacted) diisocyanates (e.g., spray applied sealants and coatings) or incidental exposures to the general population while such products are used in or around buildings, including homes or schools. In conducting this review of TDI compounds, EPA considered a number of potential actions, including regulatory actions under TSCA sections 4, 5, 6, and 8; cooperative actions with other federal agencies; and voluntary actions.

II. Introduction

As part of EPA's efforts to enhance the existing chemicals program under the Toxic Substances Control Act (TSCA)[1], the Agency identified an initial list of widely recognized chemicals, including TDI, for action plan development based on their presence in human blood; persistent, bioaccumulative, and toxic (PBT)[2] characteristics; use in consumer products; production volume; and other similar factors. This Action Plan is based on EPA's initial review of readily available use, exposure, and hazard information[3] on TDI. EPA considered which of the various authorities provided under TSCA and other statutes might be appropriate to address potential concerns with TDI in developing the Action Plan. The Action Plan is intended to describe the courses of action the Agency plans to pursue in the near term to address its concerns and does not constitute a final Agency determination or other final Agency action. Regulatory proceedings indicated by the Action Plan will include appropriate opportunities for public and stakeholder input, including through notice and comment rulemaking processes. In a concurrent action, a separate Action Plan is under development for Methylene Diphenyl Diisocyanate (MDI), a substance chemically related to TDI with similar hazard and exposure concerns.

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[1] 15 U.S.C §2601 et seq.

[2] Information on PBT chemicals can be found on the EPA web site at http://www.epa.gov/pbt/.

[3] Sources initially consulted for basic background information for all the action plan chemicals, including TDI, include Inventory Update Report (IUR) submissions; Toxic Release Inventory (TRI) reporting; data submitted to the HPV Challenge Program; existing hazard and risk assessments performed by domestic and international authorities including but not limited to U.S. Federal government agencies, the Organization for Economic Cooperation and Development, the Stockholm Convention on Persistent Organic Pollutants, Health and Environment Canada, the European Union; and others. Details about the specific sources used for this Action Plan can be found in the reference list in Section XI. of this document.

III. Scope of Review

Diisocyanates (also commonly known as isocyanates) are highly reactive and versatile chemicals with widespread commercial and consumer use. Over 90% of the diisocyanates' market is dominated by two diisocyanates and their related polyisocyanates: MDI and TDI (Allport *et al.*, 2003). They have unique properties and functional versatility, and contain free isocyanate functional groups (-N=C=O). When isocyanates are combined with other compounds that contain free hydroxyl functional groups (i.e. –OH) they react and begin to form polyurethane polymers. This chemical reaction is completed when all of the initially free –N=C=O groups are bound within the polymer network. This process is commonly referred to as "curing." Products that contain free –N=C=O groups are intended to react and undergo "curing" in the process of use. An example would be an adhesive, which is sold to be initially applied in an uncured form and as it cures (hardens), bonds two pieces of wood together. Other polyurethane products, such as mattresses, pillows, and bowling balls, are considered completely cured products before they are sold. Completely cured products are fully reacted and therefore are considered to be inert and non-toxic (Krone & Klinger, 2005). This Action Plan focuses on concerns for unreacted, uncured products.

Because of their reactivity and the diversity of uses, TDI and its related polyisocyanates (see Appendix 1) are generally supplied by their manufacturers as raw materials to formulators who take advantage of the diisocyanates' chemistry to combine them with other chemicals to create different polyurethanes with a wide diversity of applications. This diversity of applications also means that exposures to diisocyanates can occur in a broad range of production facilities from small workshops to automated production lines. Diisocyanates are potent dermal and lung sensitizers and a major cause of work-related asthma worldwide (NIOSH, 2006). Diisocyanates are also commonly available in unreacted forms as part of product mixtures widely used in construction, automotive, and other similar applications that require an end-use reaction as part of the functional performance of these products. Such applications occurring beyond the confines of a controlled production facility could result in exposures unless there is careful observance of best practices and controls to prevent exposures, including the use of protective equipment, containment, ventilation, proper clean-up practices, and medical surveillance of anyone who may be exposed.

In the past, consumer exposures have not been a focus of concern with respect to diisocyanates, because it has been assumed that consumers were generally exposed to products containing cured polyurethanes, which have been generally considered to be inert and non-toxic (Krone & Klinger, 2005). However, an increase in the consumer availability of or exposure to polyurethane products intended to further react and undergo "curing" has occurred in the marketplace (see additional discussion in section on *Consumer/General Population Exposure*). For example, consumer products, such as adhesives sealants may contain TDI compounds that are not completely reacted when applied and can provide potential exposures both to the consumer as the direct user or as a bystander to such product use by others (Krone, 2004; Bello *et al.*, 2007). In addition, certain workers (e.g., self-employed) are not subject to the applicable OSHA exposure limits, and are not legally required to receive health and safety training and chemical hazard information, or wear personal protective equipment (PPE) and therefore could potentially be overexposed to uncured polyurethane products.

EPA is concerned about the presence of uncured TDI in products used by or around consumers, as well as other unprotected building occupants, and the lack of guidance or regulations to protect them. Therefore, this Action Plan focuses on potential health effects that may result from exposures to the consumer or self-employed worker when such a person uses products containing uncured TDI, or incidental exposures to the general population when such products are used in or around buildings, including homes or schools.

IV. Uses and Substitutes Summary

MDI and TDI are the largest volume aromatic diisocyanates, are high production volume chemicals, and are predominantly used in the production of polyurethanes. In 2008, the U.S. demand for TDI was 425.2 million pounds (ACC, 2009). There are many types of polyurethane products in the marketplace, with foams representing the largest sector of the polyurethane industry. Non-foam polyurethane use sectors of TDI include coatings, adhesives, binders, and sealants. However, these products comprise a small amount of the total production volume. Polyurethane foams take two forms: flexible and rigid. Flexible foam is primarily used for cushioning, while rigid foam is used mainly for insulation. TDI chemicals are primarily used in the production of flexible foams. The majority of polyurethane products undergo curing prior to reaching the consumer. However, other polyurethane products such as coatings, sealants and adhesives may be sold and used, most often in a mixture of formulated product, in an uncured form. Researchers looking at workplace exposures to diisocyanates have noted an increase in the number of isocyanate-containing products used by consumers. These researchers also noted that community exposures to isocyanates could potentially result from industrial exposures as well as the use of consumer products containing isocyanates (Redlich, et al, 2006).

Because of its hazards, industry claims that uncured TDI is used in products intended for industrial use only (DOW, 2009). Generally, MDI and aliphatic diisocyanates have been replacing TDI in coating and adhesive products (Ott *et al.*, 2003). The 2006 Inventory Update Reporting (IUR) database indicates that TDI chemicals are used in the following consumer/commercial categories: adhesives and sealants; paints and coatings; transportation products; rubber and plastic products; wood and wood furniture; and electrical and electronic products (EPA, 2010). The Household Products Database currently lists one uncured TDI product, a concrete sealant for floors (NIH, 2010). That product and the deck coating used in an exposure study (Jarand *et al.*, 2002) are still available for purchase and it is not clear that the products are limited to professional use only. Based on online research, it appears that floor coatings and sealants are the primary types of products containing uncured TDI which might be available to consumers.

Additionally, the synthetic recreational surfacing industry uses a variety of polyurethane components in formulating its products for both indoor and outdoor surfaces (see for example, Dow, 2011). Polyurethane coatings are available for professional use to seal concrete, waterproof walls and refinish floors. So-called "for professional use" products may also be available for purchase and use by consumers or could be used in the presence of consumers. Polyurethane sealants have a variety of uses in the automotive sector, the largest being glass installation of windshields and side windows. Consumer use of adhesives and sealants is a potential growth sector as noted by an industry overview of this sector in late 2009. This growth reflects increasing numbers of DIY energy-conscious homeowners doing more of their own home renovation and repair work in order to save money, as well as from craftsmen and consumers generally continuing to use adhesives (Pianoforte, 2009). The spray foam industry, recognizing the growing use of these products by DIYers, recently developed a website on the use of spray foam with guidance directed specifically to DIYers, in addition to homeowners and professionals (ACC, 2010).

Replacement of diisocyanates in an environmentally and economically friendly manner presents a significant challenge. However, a new class of non-isocyanate polyurethanes that offers potentially safer alternatives to conventional polyurethanes has been reported by two research groups (Figovsky & Shapovalov, 2006; Javni *et al.*, 2008). Other reported technologies include an isocyanates-free expanding foam product (Soudal, 2010) and a faster curing "isocyanates-free" flexible food packaging adhesive that reportedly prevents potential migration of isocyanates into non-dry food. Of note, a soy-based adhesive intended to replace formaldehyde-urea adhesives received a Presidential Green Chemistry Award (EPA, 2009), but more research is needed to determine if soy-based adhesives would be an adequate substitute for polyurethane adhesives. While research and development of appropriate alternatives is underway with a goal of direct product substitutions, it is important to focus on the safe use of existing polyurethane products through hazard communication and educating product users.

V. Hazard Identification Summary

Environmental and Ecological Hazards. Because of their low ecotoxicity profiles, the hazards associated with exposures to TDI chemicals have centered on human health effects not ecological effects. Experimental ecotoxicological data for TDI and its degradation products indicate moderate to low toxicity to aquatic organisms (Curtis *et al.*, 1978; MITI, 1992; Tadokora *et al.*, 1997; Pedersen *et al.*, 1998). Other toxicity data suggest low likelihood of effects to terrestrial biota such as plants, earthworms (Van der Hoeven *et al.*, 1992a; Van der Hoeven *et al.*, 1992b), and birds exposed to 2,4-TDI and 2,6-TDI (IUCLID, 2000).

Toxicity in Humans. Most of the data on human health hazards resulting from diisocyanate exposures are based on occupational populations. These data indicate that exposure to diisocyanates can cause contact dermatitis, skin and respiratory tract irritation, immune sensitization, and asthma (NIOSH, 2006). Both inhalation and dermal exposures to diisocyanates are thought to contribute to the development of isocyanate asthma (Bello et al., 2007). It is well documented that isocyanate exposure is the leading cause of work-related asthma, and prevalence in the exposed workforce is estimated at 1-20% (Ott *et al.*, 2003; Bello *et al.*, 2004). Once a worker is sensitized to diisocyanates, subsequent exposures can trigger severe asthma attacks. Higher incidences of asthma are typically associated with processes that generate higher exposures, such as spray application or heated processes that generate airborne vapors and mists that can expose workers via respiratory and dermal routes. For example, the UK Health and Safety Executive reported that vehicle refinishers who spray coatings containing isocyanates have an 80 times higher risk of getting asthma compared with the UK working population. (HSE 2009) [http://www.hse.gov.uk/mvr/priorities/isocyanates.htm/]. Fewer cases of diisocyanate asthma have been reported in work settings with lower isocyanate airborne exposures, and most workers who develop diisocyanate asthma have experienced long periods of exposure (months or longer). However, the minimum exposure to isocyanates that can elicit sensitization responses or asthma is not known. In addition, immune response and subsequent disease in humans can be quite variable (Redlich *et al.*, 2006). Fatalities linked to diisocyanate exposures in sensitized persons have been reported (NIOSH, 1996; ACC, 2005). The EPA IRIS program has developed a reference concentration based on occupational exposure data (see Appendix 2)

There are very few reports of non-occupational exposures to TDI available; however, there are case reports suggesting that paraoccupational asthma may have resulted from incidental exposure to TDI (De Zotti *et al.*, 2000). In addition, antibodies to TDI have been detected in some residents living near a facility that manufactured polyurethane foam, indicating that exposures may be occurring from environmental releases from the plant and sensitizing some individuals (Orloff *et al.*, 1998; Darcey, 2002).

Toxicity in Laboratory Animals. In acute, subacute, and chronic animal exposure studies, the respiratory tract was the target organ, with nasal irritation evident at concentrations above 0.1 ppm and effects becoming more severe with increasing concentration. (Collins, 2002; ECB, 2005). TDI is uniformly distributed throughout the body, following inhalation exposure (Collins, 2002; Gledhill *et al.*, 2005). TDI causes skin, eye, and lung irritation, progressive impairment of lung function with long-term inhalation exposure and is a respiratory sensitizer via both the dermal and inhalation routes of exposure in animals (Collins, 2002). Cross-sensitization has been observed between MDI, TDI, hexamethylene diisocyanate(HDI) and dicyclohexylmethane diisocyanate (HMDI) in mice, and between MDI, TDI and HDI in humans (O'Brien *et al.*, 1979). TDI is positive in gene mutation assays *in vitro* and negative in an *in vivo* mouse micronucleus assay (Collins, 2002).

Animal data indicate that TDI may be carcinogenic (Collins, 2002). Data from recent studies of animals show that cancer is associated with exposure to commercial-grade TDI (an 80:20 mixture of 2,4- and 2,6-TDI). The responses of both rats and mice treated with TDI meet the OSHA criteria for classifying a substance as a potential occupational carcinogen (29 CFR 1990.112). NIOSH therefore recommends that occupational exposure to TDI and its isomers be minimized (NIOSH 1989).

The carcinogenic effects of TDI (Loeser 1983; NTP 1986) were also investigated by the International Agency for Research on Cancer (IARC) and the World Health Organization (WHO) (IARC 1986; WHO 1987). IARC concluded that data were sufficient to show that TDI causes cancer in animals. WHO concluded that TDI should be treated as a potential human carcinogen. In addition, NIEHS has listed TDI in its 11^{th} Report on Carcinogens as reasonably anticipated to be carcinogenic to humans.

VI. Fate Characterization Summary

Hydrolysis is the dominant process in determining the overall environmental fate, transport, and bioaccumulation potential of diisocyanates. Commercially, diisocyanates react at room temperature with other chemicals (i.e. polyols) to form various polymers. Data shows that water from humidity in air can hydrolyze TDI thus forming the amine, toluene diamine (TDA), which also has hazards associated with it. Although their rapid hydrolysis in surface water will reduce persistence and bioaccumulation in the environment (Yakabe *et al.*, 1999), under conditions of low humidity, diisocyanates may be stable long enough to be transported some distances and inhaled. Data from the Toxics Release Inventory shows releases to all media (EPA, 2008b). Despite their apparent rapid reaction time, there is uncertainty regarding diisocyanate vapors and TDA in ambient air as a function of humidity (Dyson & Hermann, 1971). Air releases are of particular concern, because the hydrolysis products formed are irritants and there is a potential for inhalation exposure.

VII. Exposure Characterization Summary

Occupational Exposure. Approximately 280,000 U.S. workers were estimated to be potentially exposed to diisocyanates in 1996 (NIOSH, 1996) but given industry growth and new applications (Bello *et al.*, 2007), this estimate is expected to be higher today. OSHA regulates workplace exposures to TDI through its permissible exposure limits (PELs) (see Appendix 2). To reduce worker exposures when exposure levels exceed its PELs, OSHA requires use of PPE when engineering controls (e.g., ventilation) or administrative controls are infeasible or fail to reduce levels adequately.

There is a potential for workplace exposure to TDI in all industrial, commercial, or manufacturing settings where TDI is present (DOW, 2009). Because of the high volatility of TDI, exposure can occur in all phases of its manufacture and use (NTP, 2005). Short-term airborne concentrations that exceed OSHA's ceiling PEL for TDI continue to be reported in polyurethane foam production facilities (Ott *et al.*, 2003), especially during upset conditions, within the foam line tunnel, or in close contact with fresh cut buns (Cummings & Booth, 2002). Overexposures to TDI were documented for floor finishing in both personal and area samples in one NIOSH evaluation (NIOSH, 2004). In another NIOSH evaluation of flexible polyurethane foam workers, although airborne exposures to TDI were below recommended exposure limits, respiratory (TDI-induced bronchitis and asthma), mucous membrane, and skin problems were noted for workers and these symptoms were associated with indicators of TDI exposure (NIOSH, 1998). Some sensitized workers susceptible to developing occupational asthma could react to isocyanate monomers at concentrations that are below 1% of the 8-hour threshold limit value (TLV) of 5 ppb for TDI/MDI (Gagne *et al.*, 2005). For TDI, NIOSH recommends exposure reduction to the lowest feasible minimum (NIOSH, 2005) and ACGIH is looking at reducing its 2011 TLVs for 2,4- and 2,6-toluene diisocyanate from current limits through a Notice of Intended Change (NIC). See Appendix 2 for numerical values.

Self-employed workers and small firms may not have access to or be aware of the hazard information and appropriate precautions to take when using uncured polyurethane products (Krone, 2004). Investigators observed workers applying a TDI-containing moisture cure urethane (MCU) floor finish without using any respiratory protection in one investigation of airborne exposures during residential application of the MCU product (ATSDR, 2005).

EPA is aware that there is uncertainty about curing time of various products under different situations and that additional data are needed to address certain concerns, such as re-entry time, which are important for improving communication to prevent exposure.

Additionally, while OSHA and NIOSH have developed methods to estimate air concentrations within workplaces, current methods underestimate air concentrations and may warrant the use of a compensation factor and/or development of improved analytical methods. Methods for detection of dermal exposure are in the early stages of development. There are several data gaps associated with dermal exposure, sensitization, and the availability of uncured isocyanate groups (Streicher *et al.*, 1998; Bello *et al.*, 2007). In the U.S., only isocyanate monomers (e.g., TDI and MDI) are regulated, although similar polyisocyanates that are widely used in commercial and consumer products contain the same reactive isocyanates. EPA is concerned that there does not appear to be sufficient recognition that potential exposures of consumers and non-OSHA regulated workers to MDI, TDI and their related polyisocyanates may need to be addressed with similar recommendations for use of engineering controls, PPE, and hazard communication as those required for OSHA-regulated occupational settings.

Consumer/General Population Exposure. Consumers, bystanders, building occupants (including children), hobbyists and DIY applicators may be exposed to uncured TDI in some products. Little information is available to document consumer use of products containing uncured TDI. It appears that over the years, MDI has been substituted for TDI in some consumer products (ACC, 2009). Although an industry product safety assessment states that uncured TDI products are intended for industrial use only (Dow, 2009), many such products are available on the Internet from formulators and distributors further down the supply chain and it is not clear if there is any control over who purchases them. Unlike workers who are protected by workplace regulations and, in most cases, have access to hazard information and training for working with diisocyanates, it is likely that most consumers are unaware of the potential hazards of consumer products containing uncured TDI. Consequently, incorrect use because of insufficient and inadequate hazard communication may lead to increased consumer exposure. Even if consumers are aware of the hazards, they may not take appropriate precautions.

While there is not much information available about direct consumer use, numerous bystander exposures to TDI products have been found in the literature, including: emissions of TDI from concrete patio sealants (Kelly *et al.*, 1999; Jarand *et al.*, 2002); and detection of TDI in building air samples following use of urethanes containing TDI to coat wood floors (NYC-DOHMH, 2010). In addition, two cases of paraoccupational TDI asthma were documented through specific inhalation challenges after the individuals were exposed to uncured TDI (De Zotti *et al.*, 2000).

Children exposed to the same levels of TDI vapor as adults may receive a larger dose because they have greater lung surface area:body weight ratios and increased minute volumes:weight ratios. TDI vapor is heavier than air and may layer close to the floor. Children who crawl, roll or sit on surfaces treated with chemicals (i.e., carpets and floors) and play with objects such as toys where residues may settle may receive higher doses of inhaled toxicants than adults present in the same room (ATSDR, 2002). Because of their relatively larger surface area:body weight ratio, children are more vulnerable to toxicants absorbed through the skin. Children may have a greater potential for exposure if they use or are bystanders to the use of uncured TDI products, because they may not have fully developed judgment for following labeling instructions and safety precautions and may not cease activity even when they are experiencing symptoms of exposure. Additionally, chronic exposure may be more serious for children because of their potential longer latency period, as they have more opportunity for both exposure to and expressions of harmful effects from exposure to substances such as TDI (ATSDR, 2001; ATSDR, 2002, EPA, 2008a). Children with asthma are an especially vulnerable population for exposure; they are more susceptible to inflammatory narrowing of the airways, which results in a proportionally greater obstruction of their smaller respiratory system (NIH, 2011; Trasande & Thurston, 2005).

In contrast to the large amount of exposure data available for professional workers who work with diisocyanates, there is limited exposure data available characterizing the use and exposure scenarios of consumer and commercial products containing uncured TDI. Additional data characterizing the concentration of TDI in the air is needed. It is unknown to what extent factors such as application techniques, product composition, and method of measurement influence the availability of uncured TDI. In addition, comparing concentrations to existing workplace exposure limits is not appropriate because the worker PEL is not sufficiently protective for the consumer (Redlich, *et al*, 2006).

IX. Risk Management Considerations

Similar types of uncured products are available for purchase by either professionals or consumers. Numerous authors have noted the versatility of polyurethane as well as its increasing uses. EPA is concerned that the potential exists for similar exposures in non-OSHA-regulated situations. Both primary users and bystanders should be made aware of the potential risks and appropriate precautions to take when uncured TDI is being used. It is unclear how many products containing uncured TDI are available for consumer purchase. However, even if uncured TDI products are being used by professionals, they could be used in locations, such as surfacing running tracks and gymnasium floors, where unintended exposure of bystanders, especially children, could be a concern. It is important to determine whether there are uncured TDI products being used in ways that could present potential exposure concerns. In addition, some personal and health care products could contain uncured diisocyanates but are beyond the scope of this action plan. However, exposures from use of such products could contribute to cumulative diisocyanate exposures (Sommer *et al.*, 2000; Donnelly *et al.*, 2003). The factors described above suggest that a heightened concern for potential risks of diisocyanate exposure to children should be addressed during actions taken to manage these chemicals.

Current and Ongoing Regulatory and Related Activities

TDI and its related polyisocyanates are the subjects of a variety of regulatory and related activities, some of which are summarized below. Additional details, including numerical values, are provided in Appendix 2.

EPA Regulatory Activities. TDI is regulated under the Clean Air Act as a hazardous air pollutant and under RCRA and CERCLA as a hazardous waste. Diisocyanates as a category and TDI individually are subject to Toxics Release Inventory reporting. Under TSCA, EPA has previously used its authority under TSCA sections 8(a) and 8(d) to request information from industry (see 40 CFR parts 712 and 716). EPA has also received submissions regarding diisocyanates under TSCA section 8(c) and TSCA section 8(e). Diisocyanates are a TSCA New

Chemicals Program Chemical Category and any new chemical substance falling in that category may be further regulated after a TSCA section 5 premanufacture notice has been submitted (EPA, 2002).

Spray Polyurethane Foam (SPF) Federal Partnership Promoting Stewardship & Research. In 2009, EPA convened a multi-agency partnership with OSHA, NIOSH, and the Consumer Product Safety Commission (CPSC) to evaluate and address potential exposures to isocyanates and other chemicals during installation of spray polyurethane foam (SPF) insulation and air sealants in homes and schools. Commercial and DIY applicators, as well as building occupants are often unaware of inhalation and dermal hazards. Applicators and others at the work site may not wear adequate PPE. Building occupants, who remain on the premises during the operations or re-enter the site before the product is fully cured may be at risk. The federal agencies are working with the polyurethanes industry to ensure accessible hazard communication, applicator training, and best workplace practices to prevent exposure to isocyanates and other SPF chemicals. In addition, the federal group has identified critical research needs to assess and measure exposures to total reactive isocyanate groups (TRIG) during use and curing of SPF products. EPA will continue to work with its federal partners, the polyurethanes industry, and others to ensure improved labeling and product safety information for polyurethane products containing unreacted isocyanates, especially products targeted to consumers. EPA is also considering a green chemistry challenge to encourage the development of safer alternative chemicals.

Canada. On May 12, 2010, Canada added TDI to its List of Toxic Substances following an assessment which determined that TDI is carcinogenic and affects the respiratory system. Environment Canada published a proposed P2 Pollution Prevention Planning Notice for the polyurethane and other foam sector. A proposed action to investigate non-foam consumer products containing TDIs under the Hazard Products Act is in development (Environment Canada, 2010).

IARC. The International Agency for Research on Cancer (IARC) has classified TDI as possibly carcinogenic to humans (IARC, 1987b).

X. Next Steps

In conducting this review, EPA considered a number of potential actions, including regulatory actions under TSCA sections 4, 5, 6, and 8; cooperative actions with other federal agencies; and voluntary actions as described above. Based on EPA's screening level review of TDI and its related polyisocyanates (Appendix 1), EPA intends to:

1. (A) Initiate rulemaking under TSCA section 5(a)(2) for a Significant New Use Rule (SNUR), designating the use of uncured TDI and its related polyisocyanates in a consumer product as a new use. As indicated in Section IV, Uses and Substitutes Summary, some members of the industry have stated that uncured TDI is not used in consumer products.

(B) If, however, public comments on the proposed SNUR indicate that there are ongoing uses of uncured TDI in consumer products, since on-going uses are by definition not new, EPA intends to consider working with industry to develop a voluntary phase-out of such uses within one year, to be followed by a SNUR.

(C) If voluntary phase-out is not agreed upon, or is not completed as agreed upon, EPA intends to consider initiating rulemaking under TSCA section 4 to require exposure monitoring studies on TDI and its related polyisocyanates in consumer products.

2. Issue a data call-in under TSCA section 8(c) to determine if there are allegations of significant adverse effects and initiate a TSCA section 8(d) rule for one-time reporting of relevant unpublished health and safety studies.

3. Consider initiating a TSCA section 4 test rule to require exposure monitoring studies in representative locations where commercial products with uncured TDI would be used.

4. Consider initiating rulemaking under TSCA section 6 to regulate commercial uses of uncured TDI products in locations where the general population could be exposed.

5. Consider identifying additional diisocyanates and their related polyisocyanates that may be present in an uncured form in consumer products that should be evaluated for regulatory and/or voluntary action.

XI. References

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Appendix 1

Tier 1: TDI monomers and related isomers and polymers

No	CASRN	CA Index Name	Acronym	Common Name
1	91-08-7	Benzene, 1,3-diisocyanato-2-methyl-	2,6-TDI	2,6-Toluene diisocyanate
2	584-84-9	Benzene, 2,4-diisocyanato-1-methyl-	2,4-TDI	2,4-Toluene diisocyanate
3	26471-62-5	Benzene, 1,3-diisocyanatomethyl-	TDI 80/20	Toluene diisocyanate
4	9017-01-0	Benzene, 1,3-diisocyanatomethyl-, homopolymer	Polymeric TDI	Poly(toluene diisocyanate)

Tier 2: TDI dimers and trimers

No	CASRN	CA Index Name	Acronym	Common Name
5	26747-90-0	1,3-Diazetidine-2,4-dione, 1,3-bis(3-isocyanatomethylphenyl)-	2,4-TDI dimer	Tolylene diisocyanate dimer
6	26603-40-7	1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(3-isocyanatomethylphenyl)-	TDI trimer	Tolylene diisocyanate trimer

Appendix 2 – Regulatory and Exposure Limits for TDI

EPA. The EPA's Integrated Risk Information System (IRIS) program has developed a reference concentration (RfC) for TDI of 7 x 10^{-5} mg/m^3 using chronic decline in lung function (FEV1) in an occupationally exposed population as the critical effect (EPA, 1995).

OSHA. Diisocyanate hazards are addressed by OSHA in specific standards for the general industry, shipyard employment, and the construction industry, including PELs for workplace exposure.

OSHA's PEL for the TDI monomer 0.140 mg/m^3 (0.02 ppm) as a ceiling limit (29 CFR 1910.1000). OSHA also requires the use of PPE to reduce worker exposure to hazards when engineering and administrative controls are not feasible or effective in reducing exposure below its PELs.

NIOSH. In 1996 and 2006, NIOSH issued Alerts to prevent asthma and death from diisocyanate exposure to workers in certain situations (NIOSH, 1996; NIOSH, 2006).

NIOSH also considers TDI to be an occupational carcinogen and recommends exposure reduction to the lowest feasible minimum (NIOSH, 2005).

ACGIH. American Conference of Governmental Industrial Hygienists. Threshold Limit Values (TLVs) for TDI address respiratory sensitivity but not dermal sensitivity. It has been suggested that there is now sufficient information to recommend the addition of a "skin notation" to the TLVs for TDI to bring attention to the potential for absorption of diisocyanates through the skin.

ACGIH has assigned TDI a TLV of 0.036 mg/m^3 (0.005 ppm) as a TWA for a normal 8-hour workday and a 40-hour workweek and a 15-minute Short Term Exposure Limit (STEL) of 0.14 mg/m^3 (0.02 ppm) (ACGIH, 2009).

As noted in its 2010 Notices of Intended Changes (NIC) for the 2011 TLVs, ACGIH is also considering reducing the TLV for 2,4 and 2,6 Toluene Diisocyanate (TDI) (CAS 584-84-9; 91-08-7) from 0.005 ppm to 0.001 ppm.

California, OEHHA. In April 2010, California's Office of Environmental Health Hazard Assessment (OEHHA) released "for comment" draft documents describing proposed Reference Exposure Levels (RELs) for TDI which have been revised to include consideration of possible differential effects on the health of infants, children and other sensitive subpopulations (California EPA, 2010)

Canada. On May 12, 2010, Canada added TDI to its List of Toxic Substances following an assessment which determined that TDI is carcinogenic and affects the respiratory system. Environment Canada published a proposed P2 Pollution Prevention Planning Notice for the polyurethane and other foam sector. A proposed action to investigate non-foam consumer products containing TDIs under the Hazard Products Act is in development.

In 2005, Canada (Ontario Province) updated and lowered its air quality standard for TDI (http://www.ene.gov.on.ca/envision/env_reg/er/documents/2005/airstandards/PA02E0010.pdf).

IARC. The International Agency for Research on Cancer (IARC) has classified TDI as possibly carcinogenic to humans (IARC, 1987b).