

***Toxics Use Reduction Institute
DRAFT POLICY ANALYSIS***

January 13, 2016

Lower Hazard Toxic Substance Designation Recommendation:

Ethyl Acetate (CAS# 141-78-6)

This policy analysis presents information related to the possible designation of ethyl acetate as a Lower Hazard Substance under TURA. The TURA Science Advisory Board (SAB) has categorized ethyl acetate in its informational list of “less hazardous chemicals,” making it a candidate for formal designation as a Lower Hazard Substance within the TURA list of Toxic or Hazardous Substances.

With this designation, the per-chemical toxics use fee for this substance would be eliminated. Facilities in TURA-regulated SIC codes using this substance above the reporting threshold would continue to report chemical use and pay the facility base fee annually, and to prepare TUR plans every two years.

This policy analysis summarizes the information used by TURI to make this recommendation. It includes scientific information about the hazards of the substance and policy information such as the number and types of facilities that are likely to be affected by this change. In providing this advice to the Council, TURI draws on recommendations and input from the Science Advisory Board and the Advisory Committee.

The goal of designating a substance in the Lower Hazard Substance category is to indicate it is less hazardous than many other TURA-listed substances. It is important to recognize that since all substances listed under TURA are hazardous, this designation does not indicate a lack of basis for concern. As with all substances listed under TURA, businesses should continue to work to reduce or eliminate the use of ethyl acetate.

1. State of the Science

The principal hazards of ethyl acetate are flammability, neurotoxicity, and irritation.

Acute toxicity

- Ethyl acetate has low acute toxicity in animal studies¹.
- Ethyl acetate is irritating to mucous surfaces, particularly the eyes, gums and respiratory passages.² Like other organic solvents, ethyl acetate is toxic to the central nervous system. Inhalation of high concentrations can cause acute neurological effects.³⁴⁵
- European Union (EU) harmonized classification under the Globally Harmonized System for the Classification and Labeling of Chemicals (GHS), for ethyl acetate:

- Eye Irritant Hazard Category 2 (adverse effects reversible within 21 days - Note: for eye effects GHS has only category 1 (irreversible damage, the most serious category) and 2); H319 - causes serious eye irritation
- STOT (specific target organ toxicity) single exposure category 3 (transient narcotic effects; central nervous system depression, including drowsiness, narcosis, lack of coordination, reduced reaction time, etc.), H336 - may cause drowsiness or dizziness, affected organs: central nervous system, route of exposure: inhalation.^{6,7}

Chronic toxicity

- As noted above, ethyl acetate is toxic to the central nervous system.
- Repeated or prolonged exposures can cause conjunctival irritation and corneal clouding. High concentrations have a narcotic effect and can cause congestion of the liver and kidneys.⁸
- The toxicity of ethyl acetate increases when in combination with certain other chemicals, such as morpholine, ethylene glycol, or ethyl alcohol.⁹
- EU harmonized classification under GHS: EUH066 - repeated exposure may cause skin dryness or cracking.¹⁰
- Ethyl acetate is negative in 36 mutagenicity studies.¹¹

Physical hazards

Flammability:

- Ethyl acetate has a flash point of 24°F (-4°C)¹², creating occupational safety concerns. This was noted by the SAB as a key concern.
- It is listed by the National Fire Protection Association (NFPA) as flammability level 3 (note: NFPA has a rating scale of 0 (not combustible) to 4 (extremely flammable liquid), which includes materials that can be “easily ignited under almost all normal temperature conditions. Water may be ineffective in controlling or extinguishing fires in such materials.”¹³
- EU harmonized classification under GHS: Hazard Category 2 flammable liquid (flash point < 23°C and initial boiling point > 35°C; note: GHS has 3 categories for flammable liquids, with category 1 being the highest flammability); H225: Highly flammable liquid and vapour.
- Ethyl acetate has caused accidents due to its flammability. For example, in 2008, a static spark ignited ethyl acetate, destroying a warehouse and requiring an evacuation of nearby businesses.¹⁴

Reactivity and explosivity:

- Ethyl acetate reacts vigorously with certain chemicals, and explosively with others (such as lithium tetrahydroaluminate).¹⁵

Environment

According to EPA's PBT profiler, it has low persistence in water and soil, medium persistence in sediment, and high persistence in air, and is toxic to fish.

Ethyl acetate's high vapor pressure of 93 mm Hg at 25C indicates strong likelihood of it existing as vapor in air. Half life in air is estimated to be 10 days.¹⁶

Ethyl acetate is a volatile organic compound (VOC), and emissions to air can contribute to photochemical smog.

Other information considered by the SAB

The Science Advisory Board considered a number of hazard endpoints for ethyl acetate in comparison with three other acetates, two that have already been designated as Lower Hazard Substances (iso-butyl acetate and butyl acetate) and one that was delisted during the CERCLA chemical review process (amyl acetate).

The SAB noted that ethyl acetate is less hazardous than the comparison chemicals for some endpoints/attributes, and more hazardous for others. It is more flammable and has more exposure potential, as it has a significantly lower flash point (24°F) and a significantly higher vapor pressure (93 mmHg @ 25°C) than the other three chemicals. The SAB noted this as an occupational safety concern.

Acute toxicity from animal studies showed it to be less hazardous or in the same range as the other three. All four have similar concerns for neurotoxicity and skin, eye and respiratory irritation, and all are VOCs. Fish toxicity is lower and persistence in air is higher than the other acetates.

Uncertainty

The hazards of ethyl acetate are relatively well understood. Uncertainty does not play a significant role in development of our policy recommendations in this case.

2. Number of facilities affected

Ethyl acetate is a solvent with a wide variety of applications and uses in Massachusetts. Uses of ethyl acetate reported under TURA include coated paper, paints, adhesives, pharmaceuticals, and chemical distribution, among others.

a. Historical data on sectors using Ethyl Acetate in Massachusetts

Historically, the following sectors have reported ethyl acetate use under TURA:

2099	Food preparations
2295	Coated fabrics, not rubberized
2671	Packaging paper and plastics film
2672	Paper coated and laminated
2679	Converted paper products
2754	Commercial printing, gravure
2821	Plastics materials and resins
2833	Medicinals and botanicals
2851	Paints and allied products
2861	Gum and wood chemicals
2865	Cyclic crudes and intermediates
2869	Industrial organic chemicals
2891	Adhesives and sealants
2893	Printing ink
2899	Chemical preparations, not elsewhere classified
3053	Gaskets, packing & sealing devices
3069	Fabricated rubber products
3081	Unsupported plastics film & sheet
3089	Plastics products, not elsewhere classified
3497	Metal foil & leaf
3714	Motor vehicle parts and accessories
3861	Photographic equipment and supplies
3949	Sporting and athletic goods
5169	Chemicals and allied products
5172	Petroleum products

b. Current TURA data on ethyl acetate use in Massachusetts

In 2012, the most recent year for which data are available, 22 companies reported the use of ethyl acetate under TURA, as shown in the table below.

SIC Code		No. of 2012 Filers	Type of Use
2671	Packaging paper and plastics film	2	Otherwise Used
2672	Paper coated and laminated	3	Otherwise Used
2821	Plastics materials and resins	2	Processed
2833	Medicinals and botanicals	2	Otherwise Used

2851	Paints and allied products	2	Processed
2891	Adhesives and sealants	1	Processed
2899	Chemical preparations, not elsewhere classified	2	Processed
3053	Gaskets, packing & sealing devices	1	Processed
3081	Unsupported plastics film & sheet	1	Otherwise Used
3497	Metal foil & leaf	1	Processed
5169	Chemicals and allied products	4	Processed
5172	Petroleum products	1	Processed

a. Trends in ethyl acetate use

Ethyl acetate use reported under TURA has increased since the program's inception. In 1991, the first reporting year for ethyl acetate, 31 TURA filers reported ethyl acetate use; in 2012, 22 reported ethyl acetate use. Peak use occurred in 1995 with nearly 13 million lbs. Peak releases occurred in 1994 with 942,990 lbs. Use increased by 15% over the period 1991 - 2012, while releases declined by 72%.

In 2012, 3.3 million lbs were processed (with 3.2 million lbs shipped in/as product) and 8 million lbs were otherwise used.

TURA Ethyl Acetate Use and Release Data: 1990 and 2012 (figures not adjusted for production)				
	Year		Change	% Change
	1991	2012	In lbs	
Ethyl Acetate used (lbs)	9,829,031	11,282,276	+1,453,245	+15%
Ethyl Acetate Released (lbs)	738,651	210,532	-528,119	-72%

3. Regulatory Context

Ethyl acetate is regulated under several statutes at the federal level.

EPCRA	<ul style="list-style-type: none"> NOT reportable under TRI¹⁷
CERCLA	<ul style="list-style-type: none"> Reportable quantity: 5,000 lb.¹⁸
RCRA	<ul style="list-style-type: none"> Reportable as hazardous waste. (RCRA Waste No. U112)
CAA	<ul style="list-style-type: none"> Regulated as a VOC (volatile organic compound) Section 111 - Standards of Performance for New Stationary Sources of Air

	Pollutants – equipment leaks chemical list. ¹⁹
CWA	<ul style="list-style-type: none"> • Section 304B – Effluent limitation guidelines
OSHA PEL	<ul style="list-style-type: none"> • 400 ppm²⁰
ACGIH TLV (TWA)	<ul style="list-style-type: none"> • 400 ppm²¹
FDA	<ul style="list-style-type: none"> • Inactive Ingredients List (for: transdermal, film, controlled release; oral solution; oral capsule, sustained action; topical solution; and others)²²

Ethyl acetate is not classified by IARC and is not on California’s Proposition 65 list.

4. Implications for the TURA program

Designation of ethyl acetate as a lower hazard substance would mean facilities no longer would be required to pay the per-chemical toxics use fee of \$1,100 for this substance. Based on 2012 reporting data, this would affect 22 facilities and the total revenue loss to the TURA program would not exceed \$24,200 based on those filing in 2012, several of which currently pay the maximum fee for their facility size. Companies would continue to report and plan for these chemicals, so the program would still receive reporting data and the companies would still gain the benefits of planning.

¹ Gigiena i Sanitariya. For English translation, see HYSAAV. Vol. 48(4), Pg. 66, 1983. As cited in ChemIDPlus; Yakkyoku. Pharmacy. Vol. 32, Pg. 1241, 1981, As cited in ChemIDPlus.

² Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 1514. As cited in Hazardous Substances Data Bank (HSDB).

³ U.S. National Library of Medicine, Haz-Map, Accessed online 12/4/2014: <http://hazmap.nlm.nih.gov/category-details?id=721&table=copytblagents>. Note: Listed as neurotoxicant, associated with CNS Solvent Syndrome. Additional information from Hazmap: “Ethyl acetate is in the list of “Some volatile substances which may be abused by inhalation” published on the web site of the U.N. International Drug Control Programme, indicating its potential to cause narcosis in workers. [Reference #1] An eye and respiratory tract irritant; Inhalation of high concentrations may cause CNS effects; [ICSC]” Reference 1 = R.J. Flanagan et al., “Volatile Substance Abuse: Practical Guidelines for Analytical Investigation of Suspected Cases and Interpretation of Results.” No. 5. Available at http://www.unodc.org/pdf/technical_series_1997-01-01_1.pdf, viewed August 12, 2014.

⁴ Centers for Disease Control and Prevention – National Institute for Occupational Safety and Health Pocket Guide, “Ethyl acetate”, Accessed online 12/10/14: <http://www.cdc.gov/niosh/npg/npgd0260.html>

⁵ USEPA Results of TSCA Section 4 Chemical Testing. downloaded “chemnamechart.wpd” dated 6/24/08, *Table summarizes test results from neurological rat studies required by EPA in 1995 and 1997 under TSCA*. Accessed online 12/8/14: <http://www.epa.gov/opptintr/chemtest/pubs/sumindex.html>.

⁶ Source: European Chemicals Agency, <http://echa.europa.eu/>, European Union ECHA Information on Chemicals - Classification and Labeling Inventory Database. Harmonized classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). Accessed online 12/10/14: <http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/95722>

⁷ “The hazard class STOT-SE has 3 categories, with Categories 1 and 2 being distinct from Category 3 in terms of the toxicity they cover and the criteria. Categories 1 and 2 for non lethal ‘significant and/or severe toxic effects’ are the basis for classification with the category reflecting the dose level required to cause the effect. Category 3 covers

‘transient effects’ occurring after single exposure, specifically respiratory tract irritation (RTI) and narcotic effects (NE).” ECHA, *Guidance on the Application of the CLP Criteria*, version 4.0, Nov 2013. Accessed on April 3, 2015 at: http://echa.europa.eu/documents/10162/13562/clp_en.pdf.

⁸ Lewis, R.J. *Sax's Dangerous Properties of Industrial Materials*. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 1514.

⁹ Clayton, G.D., F.E. Clayton (eds.) *Patty's Industrial Hygiene and Toxicology*. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994., p. 2984. As cited in Hazardous Substances Data Bank (HSDB).

¹⁰ Source: European Chemicals Agency, <http://echa.europa.eu/>, European Union ECHA Information on Chemicals - Classification and Labeling Inventory Database. Harmonized classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). Accessed online 12/10/14: <http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/95722>

¹¹ Chemical Carcinogenesis Research Information System (CCRIS), Accessed online 12/10/14: <http://toxnet.nlm.nih.gov/newtoxnet/ccris.htm>

¹² Centers for Disease Control and Prevention – National Institute for Occupational Safety and Health Pocket Guide, “Ethyl acetate”, Accessed online 12/10/14: <http://www.cdc.gov/niosh/npg/npgd0260.html>

¹³ Fire Protection Guide to Hazardous Materials. 12 ed. Quincy, MA: National Fire Protection Association, 1997., p. 325-47]. As cited in the Hazardous Substances Data Bank.

¹⁴ Chemical Safety Board Case Study No. 2008-02-1-1A (Sep 2008) “Static Spark Ignites Flammable Liquid during Portable Tank Filling Operation”, Accessed online 12/10/14: http://www.csb.gov/assets/1/19/Barton_Case_Study_-_9_18_2008.pdf

¹⁵ Fire Protection Guide to Hazardous Materials. 12 ed. Quincy, MA: National Fire Protection Association, 1997., p. 325-47]. As cited in Hazardous Substances Data Bank.

¹⁶ Atkinson R; J Phys Chem Ref Data Monograph 1 p. 166 (1989)], as cited in HSDB.

¹⁷ U.S. Environmental Protection Agency, List of Lists: Consolidated List of Chemicals Subject to the Emergency Planning and Community Right-To-Know Act (EPCRA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and Section 112® of the Clean Air Act. Accessed online 12/10/14: http://www2.epa.gov/sites/production/files/2013-08/documents/list_of_lists.pdf

¹⁸ Ibid.

¹⁹ ListEXPERT™. Expert Publishing, a division of EBSCO Publishing, Ipswich, MA. <http://www.expub.com> (accessed December 10, 2014). Note: Standards of Performance for New Stationary Sources of Air Pollutants - Equipment Leaks Chemical List. Chemicals on this list are regulated by EPA via technology-based new source performance standards (NSPS). “EPA has established NSPS for a number of industry categories including municipal waste combustors, Portland cement plants, asphalt concrete plants, incinerators, petroleum refineries, and municipal solid waste landfills. The purpose of the NSPS for emissions is to ensure that certain EPA-identified sources are designed, built, and operated in a manner that reflects the best demonstrated technology and retains economic feasibility in a uniform manner across the country.”

²⁰ Occupational Safety and Health Administration Annotated Table Z-1, Accessed online 12/10/14: <https://www.osha.gov/dsg/annotated-pels/tablez-1.html>

²¹ Ibid.

²² U.S. Food and Drug Administration, Inactive Ingredient Search for Approved Drug Products, Accessed online 12/10/14: <http://www.accessdata.fda.gov/scripts/cder/iig/getiigWEB.cfm>