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VIA ELECTRONIC MAIL AND CENTRAL DATA EXCHANGE

September 10, 2021

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Re: Economic and Toxicological Analyses in Support of ENTEK Request for TSCA Section 6(g) Exemption
TSCA Section 6 TCE Rulemaking, EPA Docket No. EPA-HQ-OPPT-2020-0642

Dear Ms. McNamara:

ENTEK[1] appreciates this opportunity to provide information[2] in relation to the U.S. Environmental Protection Agency's ("EPA") risk management rulemaking for trichloroethylene ("TCE") under Section 6(a) of the Toxic Substances Control Act ("TSCA"). As explained in our prior submittals to EPA, ENTEK is the predominant U.S. producer of lead-acid and lithium battery separators used in the batteries that power the nation. Because TCE is indispensable and irreplaceable within ENTEK's separator manufacturing process, ENTEK has requested an exemption under TSCA Section 6(g) from EPA's forthcoming proposed TCE risk management rule.[3]

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[1] ENTEK comprises both ENTEK International LLC, which produces separators for lead-acid batteries, and ENTEK Membranes LLC, which produces separators for lithium and lithium-ion batteries. Both are collectively referenced here as "ENTEK."

[2] This letter and Attachments A and B hereto contain confidential business information ("CBI"). ENTEK is publicly submitting redacted versions of these materials as non-CBI. ENTEK is concurrently submitting unredacted, CBI-containing versions via EPA's Central Data Exchange ("CDX") system.

[3] *See* Letter from Kim Medford, ENTEK, to Katelan McNamara, EPA, regarding ENTEK's Request for Section 6(g) Exemption (July 14, 2021).

TSCA Section 6(g) authorizes EPA to exempt specific conditions of use from otherwise applicable risk management rules when the criteria in subsection (1)(A), (B), or (C) are met.[4] As explained in ENTEK's previous submissions to EPA, ENTEK's specific condition of TCE use qualifies for each of the three Section 6(g) exemptions. In particular, ENTEK's use meets the criteria of:

- Section 6(g)(1)(A) because ENTEK's use of TCE is critical and essential with no available technically and economically feasible safer alternative, taking into consideration hazard and exposure;

- Section 6(g)(1)(B) because restricting or banning ENTEK's use of TCE would significantly disrupt the national economy, national security, and critical infrastructure; and

- Section 6(g)(1)(C) because ENTEK's use of TCE, as compared to reasonably available alternatives, provides substantial benefits to public health and safety.

This letter includes additional economic and toxicological information, detailed below, in support of ENTEK's exemption request.

I. Economic and Toxicological Information

a. Attachment A - Economic Support for ENTEK's Exemption Request

With this letter, ENTEK submits economic information and analysis relevant to EPA's consideration of ENTEK's exemption request. ENTEK retained eftec,[5] an international environmental economics consultancy, to conduct an independent, comprehensive economic analysis addressing the considerations justifying an exemption pursuant to TSCA Sections 6(g)(1)(A)-(B). That analysis, issued September 3, 2021 and entitled "Toxic Substances Control Act (TSCA) Economic Support" (the "Economic Report"), is provided as Attachment A to this letter.

To prepare the Economic Report, eftec utilized market data from various industry sources, including ENTEK's customers and the leading trade association, Battery Council International; multiple years of ENTEK's financial and sales information, from both ENTEK's U.S. plant and its plant in the United Kingdom; and project-specific quantitative and qualitative data provided by ENTEK's primary customers. *See* Economic Report, Section 1.3. The Economic Report was conducted consistent with EPA's 2016 "Guidelines for Preparing

[4] 15 U.S.C. § 2605(g)(1)(A)-(C).

[5] eftec has also assisted ENTEK with economic analyses in conjunction with ENTEK's authorization to use TCE under Europe's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) program. Thus, eftec is well versed in ENTEK's separator manufacturing production processes and economic considerations.

Economic Analyses" and relevant portions of the REACH program's administrative guidance for best practices in preparing Socio-Economic Analysis (SEA). The Economic Report also presents information regarding ENTEK's research and analyses of potential technically and economically feasible safer alternatives to its TCE use.

b. Attachment B – Toxicological Support for ENTEK's Exemption Request

With this letter, ENTEK also includes toxicological information relevant to its manufacturing plant in the U.S. To develop this information, ENTEK retained Gradient, an environmental and risk sciences consultancy known for its toxicology and risk assessment work. ENTEK directed Gradient to provide an independent, expert assessment of TCE exposure and associated risks at ENTEK's manufacturing plant in Lebanon, Oregon. That assessment (the "Toxicological Report") is provided as Attachment B to this letter.

As detailed in the Toxicological Report, Gradient conducted a TCE exposure evaluation reflective of workers in ENTEK's Lebanon, Oregon plant, utilizing area monitoring and personal breathing zone ("PBZ") data collected from facility workers, with consideration of ENTEK's personal protective equipment ("PPR") policies and engineering controls, and analyzed and contextualized the exposure data with respect to TCE toxicity reference values derived by EPA in its 2020 TSCA Section 6(a) Risk Evaluation for TCE.

II. The Economic and Toxicological Reports Confirm a Section 6(g) Exemption for ENTEK's TCE Use is Necessity and Appropriate

The Economic Report findings confirm (1) that banning or restricting ENTEK's TCE use would cause serious disruptions to national security, the nation's economy, and critical infrastructure sectors; (2) that ENTEK's TCE use is critical and essential; and (3) that no safer technically and economically feasible alternative is available or even likely to become available for many years.

First, the data show that banning or restricting ENTEK's TCE use would cause massive economic disruptions. Banning or restricting ENTEK's TCE use would lead to a huge shortage of lead-acid battery separators[6] which, in turn, would cause a cumulative U.S. shortage of approximately 270 million lead-acid batteries over the five-year period after EPA's TCE risk management rules take effect. That shortage would trigger a wave of disruptions along U.S. supply chains, with expected economic impacts of at least $14 billion[7] in the battery sector alone. When cross-sector effects are analyzed, the data indicate a potential total economic impact of approximately $98 billion.

[redacted]

[7] In present value, i.e., 2021 prices.

Second, eftec's analysis evinces that ENTEK's TCE use and separators produced therefrom are critical and essential to both the battery manufacturing industry and to society overall. From the industry's perspective, without access to ENTEK's separators, battery manufacturers will struggle to find a sufficient supply of suitable alternative battery separators, even on the global market. The implications to society of a potential ENTEK separator shortage are even more dire. Most heavily affected will be U.S. critical infrastructure sectors, specifically, transportation and emergency services. Domestic auto manufacturing would be gutted by the expected battery shortfall. Total costs to the road transportation and construction sectors are estimated by eftec to be about $58 billion from 2023-2028. Costs to the already strained U.S. healthcare system are estimated at about $40 billion during the same period. The costs are not purely economic. Ensuing delays in emergency service fleet response times could mean poorer health outcomes. Numerous jobs would also be lost: eftec's analysis indicates that the up-, down-, and cross-stream effects of the ENTEK separator shortage will lead thousands of Americans (between 19,900 to 33,900) to lose their jobs.

Third, eftec's report reveals that despite ENTEK's significant ongoing investments in research and development, no technically and economically feasible alternative to TCE is currently available for ENTEK's use. This conclusion draws on information developed by ENTEK over years of in-depth technical and economic feasibility evaluations, as documented in the Economic Report:

- Traditional alternative solvents like methylene chloride and hexane are neither economically feasible, nor confirmed to be technically feasible for ENTEK's specific use, and present serious health and safety risks.

- ENTEK has also assessed several newly available solvents. Only a small number of these even showed initial technical promise based on laboratory trials, but none constitutes a 'drop-in' replacement for TCE in ENTEK's use. With little information on their risk profiles, economic feasibility, or commercial-scale technical feasibility, these novel solvents are not safer technically and economically feasible alternatives to TCE.

- ENTEK also continues to explore [redacted] alternative technologies, including innovative methods to form porous films, gels, or other materials to sit directly between battery electrodes. These experimental technologies represent an entirely new way to approach battery energization and require extensive further research and development before ENTEK could identify any such technology as commercially viable, technically feasible, or "available" as contemplated under TSCA Section 6(g)(1)(A).

Accordingly, ENTEK and eftec estimate that a minimum of 14 years would be needed before any one of these potential alternatives could be proven, if at all, to be an available, safer,

technically and economically feasible alternative to TCE for adoption in ENTEK's use at its Lebanon, Oregon plant.

Finally, Gradient's Toxicological Report demonstrates that ENTEK's current PPE policies and engineering controls are protective of potential worker exposures to TCE at the Lebanon, Oregon plant.[8] The report analyzes ENTEK's worker exposure data, finding that the vast majority of representative worker exposure concentrations at the Lebanon, Oregon manufacturing plant are well below current occupational exposure limits established by Occupational Safety and Health Administration, the National Institute for Occupational Safety and Health, and American Conference of Governmental Industrial Hygienists ("ACGIH").[9] In addition, Gradient evaluated and refined EPA's toxicological assumptions for TCE, making recommendations for revisions to the TCE toxicity values for cancer and non-cancer effects to better align with actual, measured health effects in animal studies, to account for animal-to-human toxicodynamic differences, and to more accurately reflect risk evaluation for a healthy worker population.

[redacted]

///

///

[8] [redacted]

[9] Note that this information, though supportive, is not required for EPA to issue an exemption to ENTEK under TSCA 6(g).

ENTEK

CONCLUSION

We appreciate the opportunity to provide this information to EPA. We would be pleased to provide EPA with additional information on any of the points discussed in the attached reports.[10] Please feel free to reach out with any questions.

Sincerely,

Kimberly A. Medford
President, ENTEK Manufacturing
VP & General Counsel, ENTEK International & ENTEK Membranes

Encl.: Attachment A – Toxic Substances Control Act (TSCA) Economic Support, ENTEK (September 2021)
Attachment B – Trichloroethylene Exposure and Risk Evaluation, ENTEK International Facility, Lebanon, Oregon, Gradient (September 2021)

cc:

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[10] For example, ENTEK has documented its ongoing experiments and investigations on [redacted] in voluminous detail, which information can be made available to EPA upon request.

Attachment A

Toxic Substances Control Act (TSCA) Economic Support, ENTEK
eftec (September 2021)

eftec
economics for the environment

Toxic Substances Control Act (TSCA) Economic Support

Final Report

ENTEK

September 2021

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Acknowledgements

We would like to thank Peter Fisk Associates Limited for the technical work that they carried out for ENTEK concerning UK REACH on aspects such as the technical feasibility of alternatives and the ENTEK production process which is directly relevant for this work carried out for this project.

Disclaimer

While eftec has endeavoured to provide accurate and reliable information, eftec is reliant on the accuracy of underlying data provided and those readily available in the public domain. eftec will not be responsible for any loss or damage caused by relying on the content contained in this report.

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Executive summary

[redacted]

The Toxic Substances Control Act (TSCA) regulates the use of new and existing chemicals within the U.S. and is administered by the United States Environmental Protection Agency (EPA). In November 2020, EPA concluded in its final risk evaluation that TCE poses a risk to human health in certain uses, including as a "process solvent used in battery manufacture".[2] Under Section 6(a) of the TSCA, EPA has since begun proceedings to manage the TCE health risk through new rules pursuant to which EPA could require actions restricting or even banning ENTEK's access to or use of TCE at its plant in Lebanon, Oregon.

TSCA Section 6(g) authorizes EPA to grant exemptions from the otherwise applicable risk management requirements if one or more of the following criteria are met:

- The "use (of TCE) is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure"; or
- Requiring ENTEK to comply with EPA's risk management rules "would significantly disrupt the national economy, national security, or critical infrastructure"; or
- The use of TCE by ENTEK, "as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety."

This report concludes that all three exemption criteria have been met in the case of ENTEK's continued use of TCE for the production of lead-acid and lithium battery separators.

[redacted]

[2] ENTEK does not manufacture the batteries themselves.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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[redacted]

[redacted]

[redacted]

Boxes

[redacted]

Abbreviations & Acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
AfA	Application for Authorisation
AGM	Absorptive Glass Mat
AoA	Analysis of Alternatives
BCF	Bioconcentration Factor
BCI	Battery Council International
[redacted]	[redacted]
CAGR	Compound annual growth rate
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging Regulation
CNS	Central nervous system
CoRAP	Community Rolling Action Plan
DFMEA	Design Failure Mode Effects Analysis
DU	Downstream User
ECC	Electrochemical compatibility
ECHA	European Chemicals Agency
EFB	Enhanced Flooded Battery
EPA	Environmental Protection Agency
ES&H	Environment, safety & health
ESA	ENTEK Separindo Asia
EU	European Union
EV	Electric vehicle
GB	Great Britain
GB MCL	Great Britain's mandatory classification and labelling
HV	Hybrid vehicles
IARC	International Agency for Research on Cancer
i-PP	Isotactic polypropylene
IUPAC	International Union of Pure and Applied Chemistry
LEL	Lower explosive limit
LR	Low Resistance Battery Separator
MBF	Melt blown fibre
MCF	Metal Cleaning Fluid
MD	Machine Direction
MDO	Machine direction orientation
NOAEL	No-observed-adverse-effect level
NPV	Net present value
OEM	Original Equipment Manufacturers
Pb	Lead
PBT	Persistent, Bioaccumulative, Toxic
PFMEA	Process Failure Mode and Effects Analysis
PE	Polyethylene
PP	Polypropylene

PPAP	Production Part Approval Process
R	Reproductive toxicity
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAE	Society of Automotive Engineers
SCOEL	Scientific Committee on Occupational Exposure Limits
SDS	Safety data sheet
SEA	Socio-economic analysis
SEAC	European Socio-Economic Analysis Committee
SEM	Scanning electron microscope
[redacted]	[redacted]
SLI	Starting, lighting & ignition
STD	Standard Battery Separator
STEL	Short-term Exposure Limit
STOT	Specific Target Organ Toxicity
SVHC	Substance Very High Concern
TCE	Trichloroethylene
TDO	Transverse direction orientation
TSCA	Toxic Substances Control Act
UEL	Upper explosive limit
UHMWPE	Ultrahigh molecular weight polyethylene
UK	United Kingdom
U.S.	United States
VHMW-HDPE	Very high molecular weight high density polyethylene
VOC	Volatile Organic Compound
WE	Working Electrode
WEL	Workplace Exposure Limits

1. Introduction

1.1 Purpose of this study

In November 2020, the United States Environmental Protection Agency (EPA) released its evaluation that trichloroethylene (TCE), a key chemical used within ENTEK's battery separator manufacturing processes, poses a risk to human health in certain uses, including as a "process solvent used in battery manufacture". The Toxic Substances Control Act (TSCA) regulates the use of new and existing chemicals within the U.S. and is administered by the EPA. Under Section 6(a) of the TSCA, the EPA has begun proceedings to manage the TCE health risk through new rules pursuant to which EPA is authorized to require actions that could restrict or even ban ENTEK's access to or use of TCE at its plants in Lebanon, Oregon.

TSCA Section 6(g) authorizes EPA to grant exemptions from the otherwise applicable risk management requirements if one or more of the following criteria are met:

- The "use (of TCE) is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure"; or
- Requiring ENTEK to comply with EPA's risk management rules "would significantly disrupt the national economy, national security, or critical infrastructure"; or
- The use of TCE by ENTEK, "as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety."

The purpose of this study is to provide the economic data and analyses relevant to ENTEK's pending request for a TSCA Section 6(g) exemption to continue using TCE in their battery separator manufacturing processes. The study will provide evidence in support of ENTEK's exemption request and help demonstrate how the company meets the aforementioned exemption criteria. [redacted]

1.2 The Toxic Substances Control Act (TSCA)

1.2.1 General provisions: exemption criteria and economic considerations

When taking regulatory action under TSCA Section 6, balancing the effective control of risk to human health and the environment with the economic impacts of relevant regulatory actions is a key principle under the TSCA, which states that **regulatory action should not *"impede unduly or create unnecessary economic barriers to technological innovation"*** (15 U.S.C. § 2601(b)).

To mitigate economic impacts in TSCA Section 6 rulemaking, EPA considers information on health and environmental effects and the magnitude of exposure, together with:

- The **benefits associated with the use** of the substance or mixture; and
- Expected **economic consequences**, in particular the effect on (i) the national economy (ii) small businesses, and (iii) innovation (15 U.S.C. § 2605(c)).

The **cost-benefit ratio** and **cost effectiveness** of the proposed regulatory action as well as at least one of the main alternatives should be considered (15 U.S.C. § 2605(c)). A continuous evaluation of **employment effects** is also required (15 U. S. C. § 2623(a)).

TSCA Section 6(g) states that exemptions from the aforementioned regulatory actions may be granted for:

- A "critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure",
- Uses, in relation to which compliance, "would significantly disrupt the national economy, national security, or critical infrastructure", or
- A use, which "provides a substantial benefit to health, the environment, or public safety." (15 U.S.C. § 2605(g)).

1.3 Approach to the work

[redacted]

[redacted]

[redacted]

[redacted]

The analysis within the report follows the principles set out in the *Guidelines for Preparing Economic Analyses'* (EPA, 2016), which is intended to help guide economic analyses to support EPA policymaking. It further takes notes of the Socio-Economic Analysis (SEA) best practise guidance (ECHA, 2011) set out by the European Chemical Agency' (ECHA), which is the document referred to when applying for a chemical authorization under the European chemical regulatory system of REACH[5].

1.4 Structure of the report

The remainder of this report is structured as follows:

- **Section 2**: Baseline scenario
  - [redacted]
- **Section 3:** Non-use scenario
  - [redacted]
- **Section 4:** Economic impacts
  - [redacted]
- **Section 5**:Analysis of alternatives
  - [redacted]
- **Section 6**: Rationale for exemption
  - [redacted]

[5] Please note that previously the UK was part of the EU and therefore subject to ECHA's jurisdiction. However, after Brexit ENTEK is now subject to UK REACH.

2. Baseline scenario

2.1 Introduction

The section contains information on the "baseline" scenario, which is, the scenario reflecting an outcome where EPA grants ENTEK an exemption under TSCA Section 6(g) for continued use of TCE.

This section contains the following information:

- About ENTEK;
- What is a battery and what is the function of a battery separator?;
- Types of batteries;
- ENTEK's U.S. battery separator production processes and use of TCE;
- ENTEK's U.S. battery separator production processes and use of TCE

[redacted]

The manufacturing process is reliant on the properties of TCE and has been developed and adapted to efficiently recapture and reuse it.

[redacted]

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[redacted]

- [redacted]
- [redacted]
- [redacted]

The information below sets out the necessary supporting evidence base for assessing the economic impacts of continued use versus a declined exemption request.

2.2 About ENTEK

Founded in 1984, ENTEK is a global leader in the production of lead-acid and lithium battery separators. ENTEK also produces manufacturing equipment and engineering services for both battery separator production and other markets where twin screw extrusion is part of the production process, such as plastics recycling and biopolymers. [redacted]

ENTEK has manufacturing plants for battery separators in Lebanon, Oregon (USA), Newcastle-upon-Tyne, England (UK), Jakarta (Indonesia), and Tarui (Japan). Since beginning commercial production of polyethylene separators (henceforth, separators) for starting, lighting and ignition (SLI) lead-acid batteries in 1987, [redacted]

ENTEK's production of microporous separators for lead-acid batteries are primarily used within the automotive industry for the purposes of SLI and for "enhanced flooded battery"[9] (EFB), for start-stop systems in automobiles, trucks, buses, and tractors. [redacted]

[6] [redacted]

[7] ENTEK comprises both ENTEK International LLC, which produces separators for lead-acid batteries, and ENTEK Membranes LLC, which produces separators for lithium batteries. Both are collectively referenced here as "ENTEK."

[8] [redacted]

[redacted] These separators are also used in stationary battery technology for end uses in solar, wind, telecommunications, and infrastructure back-up systems.

ENTEK lithium battery separators are used predominantly to help power various devices, such as power tools and toys. They are also used in EV batteries as well as within the aerospace and military industry, with various applications (ENTEK, 2021c).

2.3 What is a battery and what is the function of a battery separator?

A battery is a container consisting of one or more cells in which energy from a chemical reaction is converted into electricity and used as a source of power. There are many different types of batteries, but generally each consists of: (i) a negative electrode material; (ii) a positive electrode material; (iii) a separator; (iv) an electrolyte that allows ions to move between the electrodes; and (v) terminals that allow electrical current to flow out of the battery (see Figure 2.1). It is the micro-porous separator that makes possible the transfer, or migration, of ions between the negative electrode and the positive electrode within the battery. This internal ion transfer is necessary to complete the battery circuit[10].

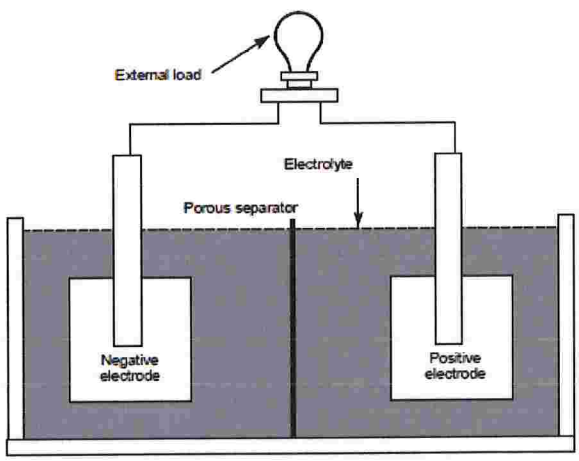

Figure 2.1: Diagram of Simple battery components

Source: engineersedge.com

Battery separators can be divided into different types depending on their physical and chemical characteristics and application. They can be moulded, woven, non-woven, micro-porous, bonded, papers, or laminates (Arora and Zhang, 2004). A wide variety of properties are required for separators used in batteries, including:

- Porosity and pore size distribution to minimize electrolyte (ionic) resistance while also mitigating dendrite formation;
- Mechanical and dimensional stability;

[10] Battery definition and explanations taken from both engineersedge.com and energizer.com

- Sufficient physical strength, including puncture resistance;
- Chemical resistance to degradation by electrolyte, impurities, and electrode reactants and products;
- Readily wetted by electrolyte;
- Effective in preventing migration of particles or colloidal or soluble species between the two electrodes; and
- Provide the correct mechanical spacing and electrolyte volume between the electrodes.

2.4 Types of batteries

Among the different varieties, batteries can be categorized in the broadest terms as primary (not rechargeable) or secondary (rechargeable) batteries.

Battery separators produced by ENTEK at their production site in Oregon (USA) are used within rechargeable lead-acid, primary lithium, and lithium-ion batteries, which are described below.

2.4.1 Lead-acid batteries

There are two different types of commercially available lead-acid battery designs: **flooded cell** and the **recombinant cell**, both of which are used in many automotive and industrial applications, including in internal combustion, hybrid, start-stop, and electric vehicles (EVs); emergency response (police, fire, and ambulances) and military vehicles; energy storage systems for renewable power generation; and backup power systems, including for hospitals and other critical public services. Both types include adjacent positive and negative electrodes that are separated from each other by a porous battery separator, as shown in **Figure 2.2**. The separators produced at the ENTEK Oregon facility - a key focus of this exemption request - are used in flooded lead-acid batteries.

The flooded cell type of lead-acid battery has only a small portion of the electrolyte absorbed into the separator. The remaining portion of the acid between the electrodes is in a continuous liquid state.

The battery separator provides a critical function within a lead-acid battery. It physically separates the positive and negative electrodes (plates) so that a short circuit cannot form, and its pore structure allows for ionic conduction through the acid between the electrodes. The porosity is created by the extraction of an extruded, oil and silica-filled polyethylene sheet with TCE. If a solid sheet of polyethylene was used, ions and electrons would not flow, and the battery would not function. The porosity of a lead-acid battery separator, provided by microscopic 'holes' through which ions can flow, is created by phase separation of the oil and polymer in the first part of the production process. The subsequent displacement of the majority of the oil with TCE, followed by its evaporation, results in the pore structure ('porosity') that allows for ion flow between the electrodes. Lead-acid battery separators are produced in a variety of different thicknesses, shapes and sizes, however, they all have the physical barrier and porosity characteristics that are critical to making a long-lasting, reliable lead-acid battery.

The separator in a lead-acid battery must also provide mechanical integrity for highspeed enveloping and prevent sharp grid wires or plates from shorting the battery during assembly. [redacted]

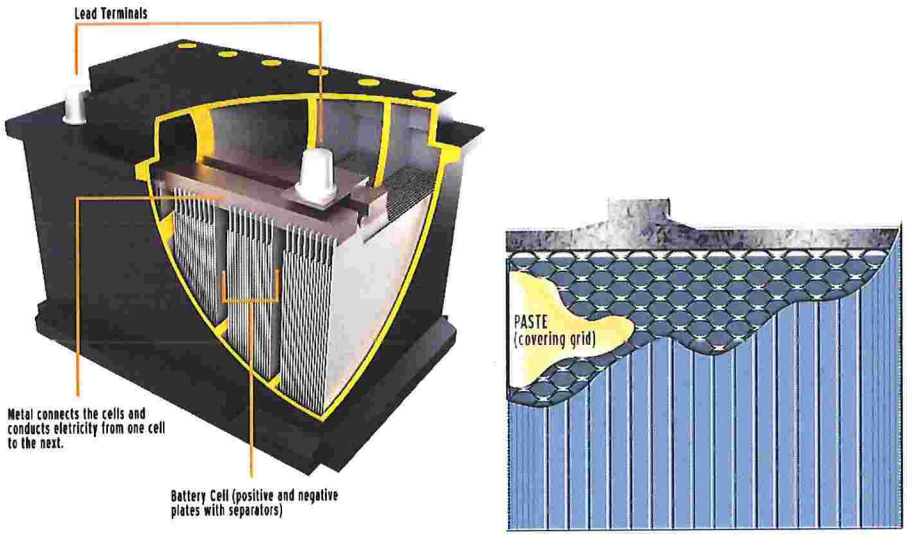

Figure 2.2: Schematic drawing of a lead-acid battery and the depiction of a separator envelope surrounding an electrode.

[redacted]

An electrode package is formed once the positive or the negative electrode is inserted into the separator envelope. The electrode package is then alternated with the other electrode (positive or negative) type to form a stack in which the separator acts as a physical spacer and an electronic insulator between the electrodes (i.e., plates). After making series and parallel connections between the electrodes and 2V cells, an electrolyte (i.e., sulphuric acid) is then introduced into the assembled battery to facilitate ionic conduction within the battery. Finally, the battery goes through an electrochemical formation step.

Separator rolls must meet a number of criteria, described as 'fit for use', in order for battery manufacturers to further process the separators at an industrial scale, as described above. [redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

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2.4.2 Lithium-ion batteries

Similar to lead-acid batteries, lithium-ion batteries are of a rechargeable type but have a significantly higher energy density. Lithium-ion batteries utilize intercalated lithium compounds in the electrodes, as part of their design, instead of metallic lithium (Wei Q. et al., 2012) in order to achieve long cycle life.

Lithium-ion batteries are comprised of four components: anode (negative electrode), cathode (positive electrode), separator, and electrolyte (Semeraro C. et al, 2021). Lithium-ion batteries often use anodes made of carbon or graphite, whereas the cathode consists of lithium cobalt oxide (LCO), lithium iron phosphate (LFP), lithium nickel manganese cobalt oxide (NMC), lithium nickel cobalt aluminium oxide (NCA), or lithium manganese oxide (LMO). The electrolyte in such batteries is made of anion salts with lithium and organic carbonates (e.g. ethylene carbonate, ethyl methyl carbonate, and/or diethyl carbonate) (Visblue, 2020). Lithium battery separators are unlike lead-acid battery separators in that they are significantly thinner (5-20 um compared to 150-250 um), do not have ribs, are not "enveloped", and contain no silica filler.

To generate energy in the battery cell, lithium ions move from the negative to positive electrode through the electrolyte while discharging and in the opposite direction while charging (Qiao H. and Wei Q., 2012).

Lithium-ion batteries are commonly installed in consumer electronics such as laptops, mobile phones, or digital cameras. This type of rechargeable battery is characterized by high energy-to-weight ratio, high open circuit voltage, low self-discharge rate and no memory effect, making them one of the most suitable batteries for portable electronics. Furthermore, lithium-ion batteries can be found in vehicles, including hybrid and EVs, and other high-power devices with rapid discharge and recharge systems (e.g., cordless power tools or drones) (Qiao H. and Wei Q., 2012). The high rate of discharge and recharge applications found in lithium-ion batteries allow them to be used in military and aerospace applications.

Lithium battery separators prevent the anode from touching the cathode (see **Figure 2.3**) and are important for preventing battery failure and safety issues (e.g., they help shut the cell down in excessive heat). For small commercial cells under abuse conditions (e.g., external short circuit or overcharge) the separator shuts down at temperatures well below where thermal runaway can occur. Shutdown results from collapse of the pores in the separator due to melting and viscous flow of the polymer, thus slowing down or stopping ion flow between the electrodes. [redacted]

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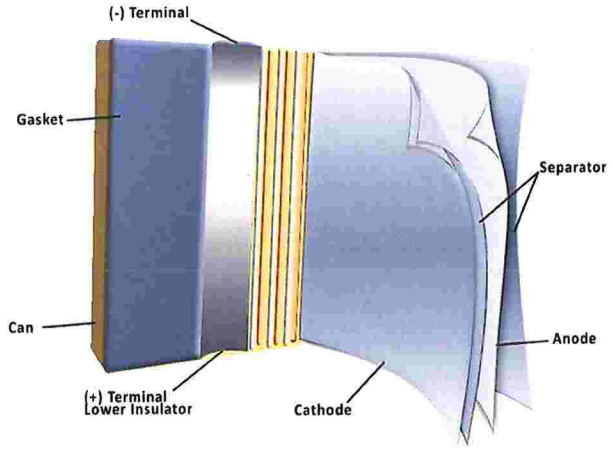

Figure 2.3: Schematic drawing of a lithium-ion battery showing the separator and electrode arrangement
Source: ENTEK (2021c)

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2.5 ENTEK's U.S. battery separator production processes and use of TCE

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The manufacturing process is reliant on the properties of TCE and has been developed and adapted to efficiently recapture and reuse it.

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TCE is essential to both ENTEK's lead-acid and lithium separator productions processes.

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2.6 ENTEK's U.S. battery separator sales

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2.7 ENTEK's customers and customer separator requirements

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2.8 Global and U.S. battery separator market

All lead-acid and lithium-ion batteries require battery separators. T[redacted]

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3. Non-use scenario

3.1 Introduction

The non-use scenario sets out the likely responses by affected parties if EPA does not grant ENTEK an exemption for the continued use of TCE. [redacted]

3.2 Possible responses to a declined exemption

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ENTEK has invested time and resources in exploring potential alternatives to the use of TCE. [redacted]

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3.3 Most likely response to a declined exemption

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4. Economic impacts

4.1 Introduction

The aim of this section is to assess the economic (and social) impacts of continued use of TCE at ENTEK's Oregon site. This is done by comparing the impacts from the exemption scenario (the baseline for this assessment), assuming continued use of TCE by ENTEK as a result of an exemption granted (set out in Section 2), with the non-use scenario [redacted]

This section assesses the net economic (and social) impacts comparing the different impacts expected to result from the exemption scenario and the non-use scenario. These form the basis of the cost analysis and stem from changes in consumer prices and producer profits.

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4.2 Impacts for ENTEK within the U.S.

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4.3 Displacement by ENTEK's U.S. based competitors

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4.4 Impacts on the lead-acid battery market

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4.5 Impacts on the U.S. economy and critical sectors

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ENTEKs lead-acid battery separators are used in internal combustion, hybrid, start-stop, and EVs; emergency response (police, fire, and ambulances), construction (e.g. support vehicles and some motive construction equipment) and military vehicles; energy storage systems for renewable power generation; and backup power systems, including for hospitals and other critical public services (ENTEK 2021d).

As set out in ENTEK's exemption letter to the EPA (ENTEK 2021d), "*Domestic automobile manufacturers rely almost exclusively on ENTEK's lead-acid battery separators. Significantly, ENTEK is the sole or majority supplier to most lead-acid battery manufacturing plants in the U.S. Moreover, the role of the battery is more important than ever as motor vehicle technology evolves toward electrification. Current estimates predict EVs will comprise 18% of new car sales by 2030, increasing battery need to eight times current factory capacity. In addition to lithium batteries, EVs also require lead-acid batteries, to manage the safety equipment that protects the lithium battery pack and to run the vehicle electronics*".

The exemption letter also explains how "*ENTEK's separators are key components used by the Defense Industrial Base critical infrastructure sector. ENTEK's separators are used in batteries serving military vehicles, weapons, and other equipment. ENTEK is a key supplier to both current providers of batteries for military applications, including for SAFT Batteries and several other early stage innovators. ENTEK's importance to U.S. national security interests was specifically recognized in response to the COVID-19 pandemic. In March 2020, the Undersecretary of Defense issued a memorandum, sent to ENTEK and other critical domestic manufacturers, stating that the company had a "special responsibility to maintain [its] normal work schedule" in order to adequately support Defense Industrial Base activities (US Department of Defense, 2020). Again, disrupting the supply of ENTEK separators used in batteries for these activities would reduce defense readiness and significantly hinder the defense base's ability to proceed under normal operating conditions, much less respond to special threats*" (ENTEK 2021d).

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As set out in ENTEK's exemption letter to the EPA (ENTEK 2021d), ENTEK separators support numerous federally designated critical infrastructure sectors (CISA, 2013), including:

- Critical manufacturing;
- Defense industrial base;
- Emergency services;
- Food and agriculture; and
- Transportation systems.

President Biden recently announced his Administration's priorities to not only protect but to strengthen these critical industry sectors and supply chains, calling on the Secretary of Energy to evaluate and report

on risks in the supply chain for "*high-capacity batteries, including electric-vehicle batteries*" and to provide "*policy recommendations to address these risks*" (US Gov, 2021a).

The Administration aims to improve the U.S.'s role "*in the supply chain associated with electric battery production,*" including by "*better leverag[ing] our ... manufacturing know-how to expand domestic battery production.*" (US Gov, 2021b) The President's American Jobs Plan furthers this priority by seeking to "*reinvigorat[e]*" domestic battery manufacturing capacity by scaling operations (US Gov, 2021c) to create a viable and independent battery supply chain (Energy Storage News, 2021). A recent 100-Day Report on these efforts focuses on lithium battery supply chains and expressly highlights that "*separators ... represent a battery supply chain stage where the United States currently relies on foreign imports due to limited domestic manufacturing capacity*" (US Gov, 2021d). Accordingly, a key goal of the U.S. Department of Energy's National Blueprint for Lithium Batteries (2021-2030) is to support the growth of midstream lithium battery manufacturing (which includes separator manufacturing) to meet domestic economic and defense demands (FCAB, 2021).

As set out in ENTEK's exemption letter, restricting or shutting down ENTEK's separator production process would leave the U.S. dangerously reliant on the importation of foreign separators, posing national security risks. Without ENTEK's Lebanon, Oregon plant, there simply is not enough domestic separator manufacturing capacity to meet current U.S. need (ENTEK 2021d).

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4.6 Unemployment impacts

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4.7 Conclusion

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5. Analysis of alternatives

5.1 Introduction

A TSCA Section 6(g) exemption requires, among other criteria, that there is no technically and economically feasible and safer alternative to TCE available for a given condition of use, taking into consideration hazard and exposure. 15 U.S.C. § 2506(g)(1)(A). ENTEK's ongoing research and development analysis has repeatedly found that **there is no alternative solvent currently available that is technically and economically feasible and safer than TCE in ENTEK's use.**

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5.2 Identification of known alternatives

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5.8 AoA summary

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6. Rationale for exemption

As set out in Section 1.1, exemptions from the EPA's risk management restrictions can be granted under Section 6(g) of the TSCA assuming certain criteria are met:

- The "use (of TCE) is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure"; or
- Requiring ENTEK to comply with EPA's risk management rules "would significantly disrupt the national economy, national security, or critical infrastructure"
- The use of TCE by ENTEK, "as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

This report concludes that **all three criteria have been met** in the case of ENTEK's continued use of TCE for the production of lead-acid and lithium battery separators.

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References

Arora and Zhang (2004). *Improved Safety for Automotive Lithium Batteries: An Innovative Approach to include an Emergency Cooling Element.* Available at: https://www.scirp.org/(S(i43dyn45teexjx455qlt3d2q))/reference/ReferencesPapers.aspx?ReferenceID=1147682

[redacted]

CISA (2013) *Presidential Policy Directive -- Critical Infrastructure Security and Resilience*. Available at: https://obamawhitehouse.archives.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil

[redacted]

ECHA (2011) *Guidance on the preparation of socio-economic analysis as part of an application for authorisation*. Available at: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/

[redacted]

ECHA (2021a) Trichloroethylene. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/14485/4/9

ECHA (2021b) (2-isobutyl-2-methyl-1,3-dioxolan-4-yl)methanol. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/9997/4/4

ECHA (2021c) 2,2-dimethyl-1,3-dioxolan-4-ylmethanol. Available at: https://echa.europa.eu/registration-

dossier/-/registered-dossier/12258

ECHA (2021d) 6,8-Dioxabicyclo[3.2.1]octan-4-one, (1S,5R)-. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/16252

ECHA (2021e) Ethyl butyrate. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/17594

Energy Storage News (2021) *Biden's US$2 trillion American Jobs Plan for infrastructure 'prioritises energy storage*. Available at: https://www.energy-storage.news/news/bidens-us2-trillion-american-jobs-plan-for-infrastructure-prioritises-energ

[redacted]

ENTEK (2021c) *Our products: Lithium.* Available at: *https://entek.com/lithium/products/*

ENTEK (2021d) – *ENTEK TSCA 6(g) Exemption request letter to the U.S Environmental Protection Agency – Dated 14th July 2021*

[redacted]

EPA (2016) *Guidelines for Preparing Economic Analyses*. Available at: https://www.epa.gov/sites/production/files/2017-08/documents/ee-0568-50.pdf

EPA (2020) *Final Risk Evaluation for Methylene Chloride* Available at: https://www.epa.gov/assessing-and-

managing-chemicals-under-tsca/final-risk-evaluation-methylene-chloride

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[redacted]

PubChem (2021a) Trichloroethylene. Available at: https://pubchem.ncbi.nlm.nih.gov/compound/Trichloroethylene

PubChem (2021b) Ethyl butyrate. Available at: https://pubchem.ncbi.nlm.nih.gov/compound/Ethyl-butyrate

PubChem (2021c) Hydrocarbons, C10-C12, isoalkanes, <2% aromatics. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/13772

[redacted]

[redacted]

[redacted]

The Volatile Organic Compounds in Paints, Varnishes and Vehicle Refinishing Products Regulations (2012). *Legislation.gov.uk.* Available at: https://www.legislation.gov.uk/uksi/2012/1715/contents

US Department of Defense (2020). *MEMORANDUM FOR DEFENSE INDUSTRIAL BASE*. Available at: https://media.defense.gov/2020/Mar/22/2002268024/-1/-1/1/DEFENSE-INDUSTRIAL-BASE-ESSENTIAL-CRITICAL-INFRASTRUCTURE-WORKFORCE-MEMO.PDF

US EPA (2003) *Toxicological review of dichloroacetic acid (CAS No. 79-43-6)* In Support of Summary Information on the Integrated Risk Information System (IRIS) August 2003 U.S. Environmental Protection Agency Washington, DC. EPA 635/R-03/007. Available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0654tr.pdf accessed April 2021

[redacted]

US Gov (2021a) *Executive Order on America's Supply Chains*. Available at: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/24/executive-order-on-americas-supply-chains/

US Gov (2021b) *FACT SHEET: Securing America's Critical Supply Chains.* Available at: https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/24/fact-sheet-securing-americas-critical-supply-chains/

US Gov (2021c) *FACT SHEET: The American Jobs Plan Supercharges the Future of Transportation and Manufacturing.* Available at: https://www.whitehouse.gov/briefing-room/statements-releases/2021/05/18/fact-sheet-the-american-jobs-plan-supercharges-the-future-of-transportation-and-manufacturing/

US Gov (2021d) *BUILDING RESILIENT SUPPLY CHAINS, REVITALIZING AMERICAN MANUFACTURING, AND FOSTERING BROAD-BASED GROWTH 100-Day Reviews under Executive Order 14017.* Available at: https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf

Visblue (2020) *What kind of batteries exist?* Available at: https://visblue.com/primary-and-secondary-batteries.html

Qiao H. and Wei Q. (2012). *Functional Nanofibers and their applications*. Available at: https://www.sciencedirect.com/book/9780857090690/functional-nanofibers-and-their-applications

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Appendix A: Efforts made to identify and analyze alternatives

A.1 Introduction

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Table A.5: Hazard profile of substance

Human Health Hazards

Acute Toxicity		
Acute toxicity	Hexane has low acute toxicity with inhalation LC_{50} value of >5000 ppm.	SUM 1995
	Acute inhalation exposure of humans to high levels of hexane causes mild Central Nervous System (CNS) depression. CNS effects include dizziness, giddiness, slight nausea, and headache in humans. Acute exposure to hexane vapours may cause dermatitis and irritation of the eyes and throat in humans.	US EPA 2000
Skin or eye corrosion/irritation	Hexane is classified as a skin irritant, however it is not classified as an eye irritant. Inhalation can cause respiratory irritation.	ECHA 2013
Respiratory or skin sensitisation	Hexane is not considered to be a sensitizing agent.	ECHA 2013
Chronic toxicity		
Carcinogenicity	EPA has classified hexane as a Group D, not classifiable as to human carcinogenicity, based on a lack of data concerning carcinogenicity in humans and animals. It is not classified by International Agency for research on Cancer (IARC).	US EPA 2000
Long term toxicity	The main effect of repeated exposure to hexane in laboratory animals and in humans is characterized by neurotoxicity. The clinical signs of neurotoxicity from hexane include limb weakness progressing to paralysis.	SCOEL 1995
	In humans repeated exposure to inhaled hexane resulted in sensorimotor polyneuropathy, with numbness in the extremities, muscular weakness, blurred vision, headache, and fatigue observed.	US EPA 2000
Reproductive and developmental toxicity	Testicular damage has been observed in male rats exposed to hexane via inhalation. Rats exposed chronically exposed to hexane via inhalation showed CNS effects and decreased body weight at concentrations at which maternal toxicity was also observed (1500 ppm or 5370 mg/m^3).	SCOEL 1995
Mutagenicity	Hexane is considered a weak mutagen in the absence of metabolic activation.	ECHA 2013
Endocrine disruption	No information	
Neurotoxicity	Neurotoxic effects to both the peripheral and the central nervous systems of humans may occur after exposure to hexane.	HSDB, 2013
Immune system toxicity	No information	
Systemic toxicity	yes, effects to the peripheral and central nervous system.	
Cardiotoxicity	Sub-cutaneous exposure of rats to 0.1 ml hexane for 30 days resulted in cardiotoxicity. 90 days subcutaneous exposure to 0.1 ml of hexane resulted in lowered ventricular fibrillation threshold and	ECHA 2013

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	lowered levels of magnesium, potassium, and zinc in rats.	
Toxic metabolites	The main metabolite of hexane is 2-5,hexanedione, a neurotoxic agent.	SCOEL 1995
Environmental effects/toxicity		
Degradation	100% degradation has been achieved after 4 weeks in a Japanese MITI test.	HSDB, 2013
Bioaccumulation	The calculated bioconcentration factor (BCF) is 501.87. It does not meet the criteria for B in persistent, bioaccumulative and toxic (PBT). However, the log K_{ow} is greater than 3, therefore the substance has potential for bioaccumulation.	ECHA 2013
Acute/chronic aquatic toxicity	There are no aquatic toxicity data with hexane in the disseminated dossier, however the substance is classified as Aquatic Chronic 2 under CLP.	ECHA 2013
	Fish toxicity LC_{50} values have been reported as low as 2.5 mg/l with *Pimephales promelas*. An invertebrate EC_{50} value of 45 mmol/m^3 has been reported with *Daphnia magna* and an algal EC_{50} value of 94 mmol/m^{3}has been derived with *Chlamydomonas angulosa* (green algae).	HSDB 2013
Greenhouse gas formation potential	Hexane is not identified as a greenhouse gas.	
Ozone-depletion potential	Hexane is not classed as an ozone depleting substance.	Regulation (EC) No 2037/2000

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Hexane is metabolised to 2-5,hexanedione, a neurotoxic agent. Acute exposure to hexane can cause respiratory and skin irritation, and effects to the central and peripheral nervous systems (such as dizziness), which may result in damage to peripheral nerves. The substance is in fact classified for acute effects under European regulation as an Aspiration Toxicant 1, Skin Irritant 2 and Specific Target Organ Toxicity Single Exposure (STOT SE) 3, with the associated hazard statements, amongst others, H335 and H336 (may cause respiratory irritation and may cause drowsiness or dizziness).

The main effect of repeated exposure to hexane is neurotoxicity, which may progress to paralysis. It may also cause testicular damage and maternal toxicity. It is classified in Europe as a Reproductive and organ toxicant and is therefore not considered to be a safe substance from a human health point of view.

In addition, hexane has the potential to bioaccumulate in the environment (log K_{ow} >3), even though it does not meet the criteria for B in PBT due to its bioaccumulation factor being below the threshold value for B (501.9 against the cut-off value of 2000 L/kg) and it is toxic to fish in short-term toxicity studies with the lowest LC50 value of 2.4 mg/L (no long-term aquatic toxicity data are available).

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Table A.8: Classifications for methylene chloride from CLP - according to Regulation No 1272/2008 Annex VI

Classification area	Harmonised	Self-classification
Physicochemical	Not classified	Not classified
Health	Carc. 2	Carc. 2
		Skin Irrit. 2
		Eye Irrit. 2
		STOT SE 3. Affected organs: central nervous system Route of exposure: inhalation
Environmental	Not classified	Not classified
Hazard Statements	H351: Suspected of causing cancer	H351: Suspected of causing cancer
		H315: Causes skin irritation
		H319: Causes serious eye irritation
		H336: May cause drowsiness or dizziness

In addition, EPA in its 2020 Section 6 risk evaluation for methylene chloride found the substance poses an unreasonable risk to both workers and occupational non-users when used as a processing aid in commercial and industrial manufacturing (EPA, 2020). Specifically, EPA determined methylene chloride posed an unreasonable risk of non-cancer effects from both acute and chronic inhalation exposures for workers and occupational non-users, even when assuming use of PPE. EPA also found an unreasonable risk of cancer from chronic occupational non-user inhalation exposures. Accordingly, at the time of publication, EPA is concurrently engaged in TSCA Section 6(a) rulemaking to determine appropriate risk management regulations for methylene chloride as well.

Table A.9: Classifications for methylene chloride from Dangerous Substance Directive – according to Directive 67/548/EEC

Classification area	Harmonised	Self-classification
Health hazards	Carc. Cat. 3; R40	Carc. Cat. 3; R40
		Xi; R36/38
Risk Phrases	R40: Limited evidence of a carcinogenic effect	R40: Limited evidence of a carcinogenic effect
		R36/38: Irritating to eyes and skin
		R67: vapours may cause drowsiness and dizziness

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Table A.11: Hazard profile of methylene chloride

Chemical Properties	Characteristics of Chemical	Source(s) of Information
Human Health Hazards		
Acute toxicity	Oral and dermal toxicity (>2000 mg/kg) and inhalation toxicity (calculated 4 h LC50 86 mg/L).	ECHA, 2013
	The predominant effects in humans are Central Nervous System (CNS) depression and elevated blood carboxyhaemoglobin (CO-Hb) levels. These acute effects are reversible. Other target organs include the liver and, occasionally, the kidney.	IPCS, 1996
Skin or eye corrosion/irritation	Dermal contact causes a burning sensation, numbness, coldness and pain. Eye contact with vapour can cause irritation. Contact with liquid methylene chloride may cause corneal burns.	Heath Protection Agency IM sheet, 2011
	Methylene chloride has been self-classified as a skin and eye irritant.	ECHA, 2013
Respiratory or skin sensitization	Not sensitizing	SIAP, 2011 and ECHA, 2013
Chronic toxicity		
Carcinogenicity	Carcinogenicity studies in rodents have shown an increase in liver and lung cancer (when exposed to7100 and 14 100 mg/m^3) and benign mammary gland tumors following inhalation exposure to methylene chloride. The relevance of the animal findings in humans is uncertain. From epidemiological studies methylene chloride is not expected to be a human carcinogen.	ATSDR, 1998 IPCS, 1996 and HSDB, 2010 ECHA, 2013
Long term toxicity	The predominant effects following repeated or long-term exposure to methylene chloride are the same as for acute exposure. Mostly reversible symptoms of CNS depression are seen in several species, including humans. Liver effects have also been reported in animals following exposures as low as 25 ppm [88 mgm^{-3}] (continuous exposure). The chronic NOAEL from an inhalation rat bioassay was 200 ppm (695 mg/m^3) based on histopathological lesions in the liver and mammary tissue.	IPCS, 1996 ECHA, 2013
Mutagenicity	Overall, the substance is not considered to be mutagenic *in vivo*.	SIAP 2011
	Methylene chloride was positive in two strains of bacteria with and without metabolic activation, and was found to cause chromosomal aberrations in mammalian cells *in vitro* at concentrations causing cytotoxicity. The substance has not been classified as a mutagen.	ECHA, 2013

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Neurotoxicity	Effects on the CNS have been observed in both animals and humans.	IPCS, 1996
Immune system toxicity	Guideline inhalation study on rats indicated NOAEL >5187 ppm for immunotoxicity parameters.	ECHA, 2013
Systemic toxicity	The lowest NOAEL for neurotoxic effects in rats from chronic inhalation is 200 ppm.	ACGIH, 2001
Toxic metabolites	Biological activation of methylene chloride to toxic metabolites. The major oxidative (saturable) pathway leads to carbon monoxide. A minor reductive (glutathione-dependent) pathway leads to potentially reactive metabolites, such as formaldehyde.	SCOEL, 2009
Reproductive/developmental	No studies were located regarding developmental or reproductive effects in humans from inhalation or oral exposure. Animal studies have demonstrated that methylene chloride does not affect reproduction (fertility) parameters; it crosses the placental barrier, and minor skeletal variations and lowered fetal body weights have been noted in the presence of maternal toxicity.	ATSDR, 1998 ECHA, 2013 HSDB, 1993
Environmental Hazards		
General	Methylene chloride is naturally formed at levels exceeding industrial production	Baker, *et al.*, 2001.
Acute/chronic aquatic toxicity	Methylene chloride is acutely toxic to aquatic invertebrates in the range 10 and 100 mg/L.	SIAP 2011
Bioaccumulation	Methylene chloride is not expected to bioaccumulate	SIAP 2011
Persistence	Methylene chloride is not readily biodegradable. However, biological degradation processes have been identified capable of mineralizing methylene chloride in a few days. Main route of elimination is hydrolysis in the atmosphere.	IPCS, 1996
Greenhouse gas formation potential	Methylene chloride is degraded to carbon dioxide and hydrogen chloride as major breakdown products. Therefore, some contribution to greenhouse gas is expected.	IPCS, 1996
Ozone-depletion potential	Methylene chloride is not classified as an ozone depleting substance.	Regulation (EC) No 2037/2000
Monitoring - has the substance been found in human or environmental samples?	In ambient air in rural and remote areas, background levels of 0.07-0.29 $\mu g/m^3$ have been measured. In suburban and urban areas levels up to 2 and 15 $\mu g/m^3$ have been found. Concentrations have been reported in the range below 10 µg/L in the surface water of rivers in industrialized areas and up to 200 mg/L in industrial effluents, outfalls of municipal water treatment plants and leachates of landfills. Monitoring data typically fails to discriminate natural methylene chloride from industrial.	IPCS, 1996

Short-term effects as a result of inhalatory exposure to methylene chloride vapours may cause CNS depression manifested through dizziness and drowsiness. The substance has been self-classified as STOT SE 3 under CLP with the associated hazard statement H316: may cause drowsiness or dizziness. Its vapours may cause eye irritation and skin contact may also cause irritation and has been classified under CLP.

When heated to decomposition methylene chloride will produce phosgene, hydrogen chloride gas, and chlorine gas which are toxic. In addition, it is metabolised to carbon monoxide, carbon dioxide and inorganic chloride (HSDB, 2010) in the body, which can result in secondary poisoning. Animal data suggests that the substance may cause liver and lung cancer.

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Appendix B: List of substitution related activities for potential alternatives

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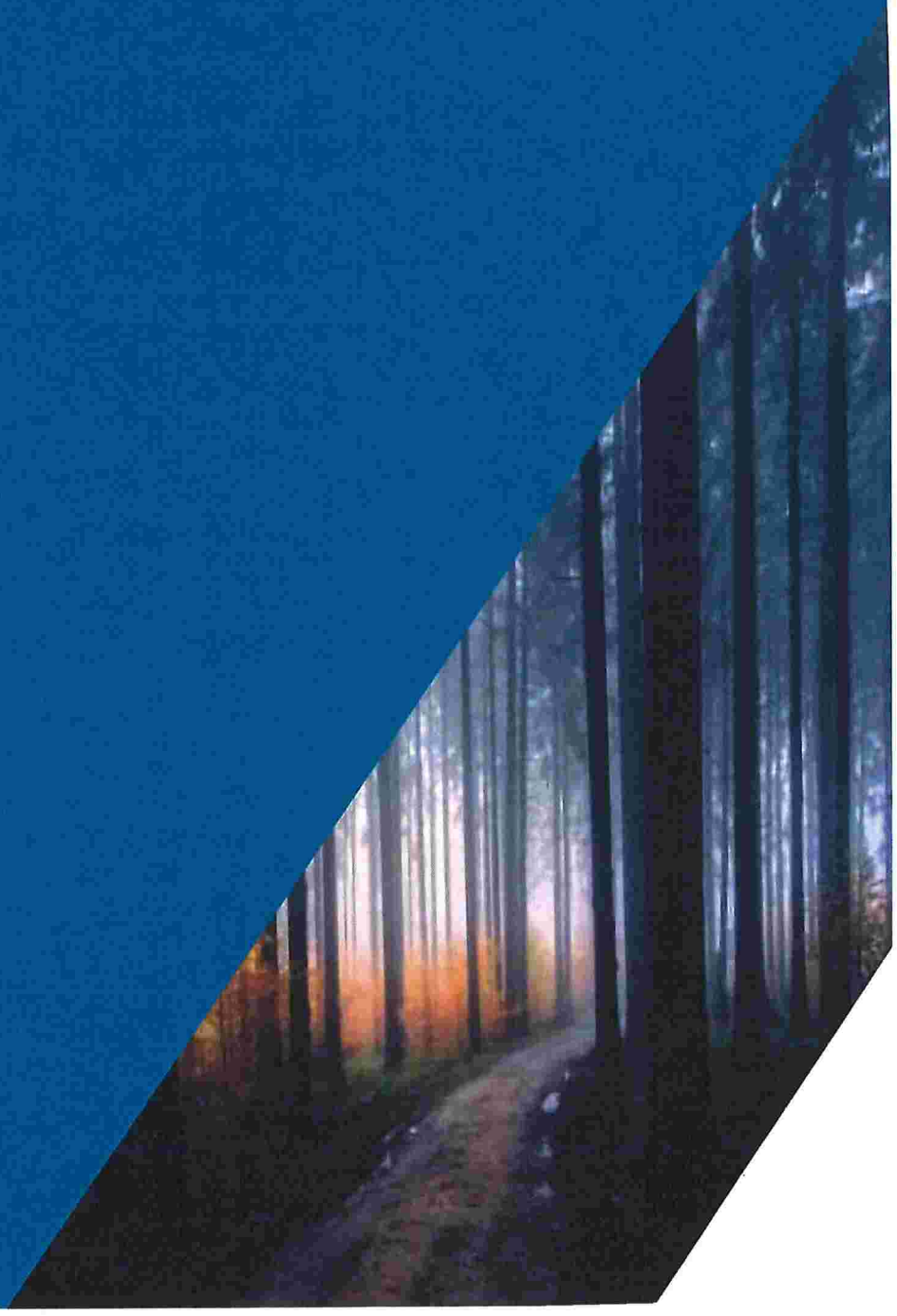

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Final report | September 2021

Attachment B

Trichloroethylene Exposure and Risk Evaluation, ENTEK Facility, Lebanon, Oregon Gradient (September 2021)

CONFIDENTIAL

Trichloroethylene Exposure and Risk Evaluation
ENTEK International Facility
Lebanon, Oregon

Prepared for
ENTEK International
250 Hansard Avenue
Lebanon, OR 97355

September 9, 2021

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Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
APF	Assigned Protection Factor
ATSDR	Agency for Toxic Substances and Disease Registry
BMDL	Lower Confidence Limit on the Benchmark Dose
dsDNA	Double-stranded DNA
EC	European Commission
EDO	Extraction, Dryer, and Oven
ENTEK	ENTEK International LLC and ENTEK Membranes LLC
GSH	Glutathione
HEC	Human Equivalent Concentration
LOAEL	Lowest Observed Adverse Effect Level
MOE	Margin of Exposure
NIOSH	National Institute for Occupational Safety and Health
OEL	Occupational Exposure Limit
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically Based Pharmacokinetic
PBZ	Personal Breathing Zone
PEL	Permissible Exposure Limit
POD	Point of Departure
PPE	Personal Protective Equipment
REL	Recommended Exposure Limit
SEG	Similarly Exposed Group
ssDNA	Single-stranded DNA
TCE	Trichloroethylene
TLV	Threshold Limit Value
TSCA	Toxic Substances Control Act
TWA	Time-weighted Average
UF	Uncertainty Factor
UK	United Kingdom
US EPA	United States Environmental Protection Agency

1 Introduction

ENTEK International LLC manufactures separators for lead-acid batteries, and ENTEK Membranes LLC manufactures separators for lithium and lithium-ion batteries at co-located facilities in Lebanon, Oregon (Lebanon facility).[1] A separator is a porous film or sheet that prevents electronic shorts but allows for ionic conduction between the positive and negative electrodes in a battery. Although the manufacturing processes at the Lebanon facility for each type of separator are different, they both utilize trichloroethylene (TCE) [redacted] ENTEK has asked Gradient to provide a TCE exposure and risk evaluation for workers at the Lebanon facility as the United States Environmental Protection Agency (US EPA) considers risk management decisions in response to its TCE Toxic Substances Control Act (TSCA) risk evaluation (US EPA, 2020).

US EPA (2020) conducted a TCE risk evaluation under TSCA to determine if TCE presents "unreasonable risk of injury to health or the environment, under the conditions of use, without consideration of costs and other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations, identified as relevant to the Risk Evaluation." US EPA reported unreasonable risks from TCE inhalation and dermal exposures for a use scenario that may be relevant to ENTEK (*i.e.*, the "Industrial Processing Aid" use scenario, under the subcategory "Process solvent used in battery manufacture"[2]). Therefore, Gradient conducted an exposure evaluation reflective of workers in the Lebanon facility, including recent area monitoring and personal breathing zone (PBZ) data collected from facility workers, with consideration of personal protective equipment (PPE) (glove and respirator use).

This report provides: 1) an overview of the ENTEK Lebanon facility's current operations and improvements made over time to protect worker health; 2) a worker exposure evaluation based on representative TCE area monitoring and PBZ data; 3) a review of US EPA's TCE hazard evaluation and recommendations for modifications to the TCE toxicity values for quantifying potential TCE human health risks for a worker population; and 4) consideration of measures ENTEK may employ to further reduce TCE exposure and potential health risks.

[1] Together, ENTEK International LLC and ENTEK Membranes LLC are referred to herein as "ENTEK."
[2] ENTEK does not manufacture batteries.

2 Plant Information

2.1 Overview of Operations

Based on input from ENTEK, and as discussed in a letter from ENTEK to US EPA (ENTEK, 2021a), here we provide an overview of ENTEK's operations.

ENTEK's lead-acid battery separators are made of precipitated silica, a naphthenic process oil, and ultrahigh molecular weight polyethylene, a unique polymer that is extruded into sheet form using the process oil. In the case of lithium separators, high-density polyethylene, the same naphthenic process oil, and ultrahigh molecular weight polyethylene are combined to form a slurry that is fed to a twin-screw extruder to form a thin, biaxially oriented film (ENTEK, 2021a).

[redacted]

TCE – the solvent ENTEK uses – is essential to ENTEK's lead-acid and lithium separator manufacturing processes. TCE has a unique combination of chemical properties that facilitate the controlled removal of process oil while allowing ENTEK to efficiently recover and recycle previously used TCE for reuse in both processes in a manner that minimizes worker exposure while resulting in a product with the characteristics demanded by the battery customers (ENTEK, 2021a). [redacted]

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The Lebanon facility is divided into two operations: one for the manufacture of battery separators for lead-acid batteries and the other for the manufacture of separators for lithium batteries (ENTEK, 2021a).

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2.2 Improvements Over Time

In 2004 and 2005, NIOSH performed initial and follow-up surveys to measure, in part, airborne TCE concentrations in the Lebanon facility in order to estimate occupational airborne exposures to TCE. The NIOSH (2008) study reported TCE exposure concentrations below the shift-adjusted OSHA PEL[5] of 67 ppm, but above the shift-adjusted NIOSH REL[6] of 21 ppm and ACGIH TLV[7] of 6.7 ppm. NIOSH (2008) recommended the use of engineering controls and respirators to reduce TCE exposure to levels below the NIOSH REL.

Since then, ENTEK has completed significant additional engineering, occupational, and administrative improvements to reduce plant worker exposures to TCE. ENTEK's current engineering controls are briefly summarized as follows.

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3 Exposure Evaluation

Human health risk evaluation involves the presence of a potential human exposure pathway (*e.g.*, inhalation or dermal contact), a potentially exposed receptor (*e.g.*, worker), and a point or area of potential contact between a receptor and the exposure medium (*e.g.*, indoor air). [redacted]

3.1 Exposure Groups

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3.2 Exposure Pathways and Assumptions

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3.2.1 Dermal

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3.3 On-site Monitoring Data Summary

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3.4 Personal Breathing Zone Data Summary

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3.5 Application of Area-to-PBZ Ratios to Estimate PBZ Concentrations

[redacted]

3.5.1 Area-to-PBZ Ratios

[redacted]

[redacted]

3.5.2 Worker Monitored and Estimated PBZ TCE Exposure Concentrations

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4 Hazard Evaluation

As part of the hazard evaluation, Gradient reviewed the toxicity reference values derived by US EPA for TCE in its recent TSCA risk evaluation (US EPA, 2020). We reviewed the basis of the point of departure (POD) values, including the health effect study applied in the derivation of the POD and human equivalent concentrations (HECs), and the basis for application of several uncertainty factors (UFs) used to determine the target margins of exposure (MOEs) for non-cancer effects.

Below we summarize the basis of US EPA's cancer and non-cancer TCE toxicity values that were used in its risk evaluation (US EPA, 2020). We then discuss Gradient's recommendations for revisions to the TCE toxicity values for cancer and non-cancer effects. We also discuss the basis of the current OELs.

4.1 TCE Toxicity Values Derived by US EPA

US EPA considered both cancer and non-cancer health endpoints from both chronic and acute TCE exposures (US EPA, 2020). US EPA evaluated several health endpoints potentially related to TCE exposure: developmental effects, immunotoxicity, reproductive toxicity, neurotoxicity, kidney toxicity, liver toxicity, and cancer (US EPA, 2020). Based on the overall weight-of-evidence evaluation, US EPA identified immunotoxicity as the most sensitive non-cancer endpoint[11] for both acute and chronic exposures.

To derive its non-cancer toxicity value for the immunotoxicity endpoint, US EPA relied on the Keil *et al.* (2009) study that evaluated increased anti-double-stranded DNA (anti-dsDNA) and anti-single-stranded DNA (anti-ssDNA) antibodies, biomarkers of autoimmune disorders in several mouse strains, including one that is considered prone to autoimmune responses, with the overall goal of the study to represent a genetically sensitive rodent population with a predisposition to autoimmune effects.

TSCA is specifically designed to regulate chemical substances that present or will present an "unreasonable risk of injury to health or the environment" (US Congress, 2016). However, the immunotoxicity POD that US EPA used in the TSCA risk assessment is based on measurements of serum biomarkers of health effects in animals, and not based on measurements of actual health effects in the animals. In addition, the Agency for Toxic Substances and Disease Registry (ATSDR) states that "TCE did not appear to contribute to the progression of autoimmune disease in the autoimmune disease-prone strain, but may have increased expressions of markers associated with autoimmune disease in the B6C3F1 strain" (ATSDR, 2019). ATSDR also notes that "biomarkers of effect are not available for TCE," and describes various biomarkers of exposure and effect for nervous system effects and kidney damage that have been reported in the literature, but does not describe biomarkers for immunotoxicity for TCE (ATSDR, 2019). Furthermore, several epidemiology studies described in the US EPA risk evaluation observed immunotoxicity biomarkers of effects (*i.e.*, alteration of immune parameters, such as changes in cytokine levels, serum antibody levels, and immune cell populations) only at exposure levels much higher than the HECs for immunotoxicity biomarkers of effects in the animals. These studies are summarized in US EPA's risk evaluation (US EPA, 2020) and in the recent toxicological profile for TCE conducted by ATSDR (2019). Two studies reported a Lowest Observed Adverse Effect Level (LOAEL) of 12 ppm (Lan *et al.*, 2010; Hosgood *et al.*, 2012),

[11] Note that while the POD for developmental effects is lower than immunotoxicity, US EPA has low confidence in the overall scientific evidence for the developmental effects endpoint (US EPA, 2020). As described by US EPA, developmental effects were only observed in one study, and the POD could not sufficiently be derived due to the lower data quality; therefore, US EPA excluded developmental endpoints in its risk evaluation (US EPA, 2020).

while one study reported a LOAEL of 5 ppm (Zhang *et al.*, 2013). The current epidemiology studies described by ATSDR (2019) did not evaluate lower TCE exposure concentrations. Therefore, the POD for immunotoxicity that US EPA used in its TSCA risk evaluation, which is based only on markers of effect and not actual disease in animals and is much lower than levels where effects have been reported in humans, is overly conservative and a re-evaluation is needed.

The next most sensitive chronic non-cancer endpoint for TCE described by US EPA in its evaluation is kidney toxicity. The chronic toxicity value that US EPA derived for non-cancer kidney effects is based on a study by Maltoni *et al.* (1986), which observed renal tubular pathological changes (meganucleocytosis) in rats exposed to TCE *via* inhalation. This endpoint is a more appropriate endpoint to apply in the TCE risk evaluation than the immunotoxicity endpoint that US EPA used, because the kidney toxicity endpoint is based on actual measurements of pathological changes and not biomarkers of effect. The POD for kidney toxicity was calculated using a lower confidence limit on the benchmark dose (BMDL) derived from the animal study. A TCE physiologically based pharmacokinetic (PBPK) model was applied to the PODs to derive HECs. US EPA applied a UF_A of 3 to account for animal-to-human toxicodynamic differences and a UF_H of 3 to account for human-to-human toxicodynamic differences. The total UF (UF_A x UF_H) is rounded to 10, which is the target MOE US EPA used in its kidney toxicity risk calculations. However, this UF is overly conservative. UFs for human-to-human variability are recommended for the general population where toxicity values need to be protective for sensitive subpopulations, such as for children or elderly populations. For healthy worker populations (such as ENTEK workers), a UF for sensitive populations is overly conservative. Therefore, Gradient recommends removal of the UF_H of 3 for healthy worker scenarios.

With respect to the UF_A of 3 to account for animal-to-human toxicodynamic differences, potential toxicodynamic differences between animals and humans are generally thought to reflect potential differences in mechanism between animals and humans. Since TCE metabolism has been extensively studied in both animals and humans, and TCE metabolism is generally thought to be directly connected to its mechanisms of adverse health effects, application of the TCE PBPK model that accounts for metabolic differences between animals and humans (as was done in US EPA's TCE risk evaluation [US EPA, 2020]) likely also accounts for potential toxicodynamic differences between animals and humans. In addition, as discussed in US EPA's guidance for derivation of oral reference doses (US EPA, 2011a), the use of body weight scaling to the ¾ power to derive an HEC from the animal POD (as was done in US EPA's TCE risk evaluation [US EPA, 2020]) addresses "predominately toxicokinetic and some toxicodynamic aspects of the interspecies uncertainty factor." Therefore, given that US EPA used a ¾ body weight scaling adjustment to estimate the human dose from the animal POD, and that US EPA then accounted for differences in TCE metabolism between animals and humans through use of a TCE PBPK model, the toxicity values that US EPA derived should already account for toxicodynamic differences between animals and humans. Therefore, Gradient recommends that the UF of 3 to account for animal-to-human toxicodynamic differences is overly conservative, particularly for a healthy worker population, and is not needed.

In addition, use of the HEC_{99}, as opposed to an HEC_{90} or HEC_{50} (*i.e.*, a 99%, 90%, or 50%, respectively, likelihood that an individual will have an internal TCE dose lower than or equal to the POD derived from the animal studies), adds an additional layer of conservatism in the TCE risk calculations. US EPA used the PODs for the non-cancer endpoints to derive HECs at which there is a 50% and 99% likelihood that an individual will have an internal TCE dose lower than or equal to the POD derived from the animal studies (HEC_{50} and HEC_{99}, respectively). The recommended HEC_{50} and HEC_{99} values based on kidney toxicity are 0.19 and 0.025 ppm, respectively (US EPA, 2020). US EPA relied on the HEC_{99} for calculating non-cancer risks because it is expected to account for interindividual variability (*i.e.*, sensitive populations). However, as previously noted, for healthy worker populations (such as ENTEK workers), the protection of a sensitive individual is overly conservative. Therefore, Gradient recommends using the HEC_{50} when evaluating risks for healthy worker scenarios.

Finally, the POD for kidney toxicity is also likely protective of cancer. This is because there is little evidence for direct DNA genotoxicity/mutagenicity of TCE, with only TCE metabolites from the glutathione (GSH) pathway showing clear evidence of genotoxicity and potential mutagenicity (US EPA, 2011b, 2020). Studies of TCE metabolism also provide evidence that the flux through the GSH pathway is much lower than the flux through the oxidative pathway (US EPA, 2011b), suggesting that flux through the GSH pathway may not contribute much to the overall TCE metabolism until high exposure concentrations when the oxidative pathway becomes saturated. Therefore, these studies suggest that the GSH metabolites will not be generated until high TCE exposure concentrations. TCE oxidative metabolites (*e.g.*, trichloroethanol [TCOH] and trichloroacetic acid [TCA]) have also been shown to be related to non-cancer kidney toxicity (US EPA, 2011b). Therefore, kidney toxicity, likely caused predominantly by non-genotoxic/non-mutagenic oxidative metabolites generated by the TCE oxidative metabolism, can be considered a threshold marker of TCE exposure below which the potentially genotoxic/mutagenic GSH metabolites are not likely to be generated. Therefore, derivation of a kidney non-cancer toxicity value based on a no-effect-level in humans should also be protective of potential genotoxic/mutagenic and carcinogenic effects of TCE.

Based on the best available scientific information for TCE described here, kidney toxicity is a more appropriate endpoint to apply in derivation of a TCE toxicity value than the immunotoxicity endpoint since it is based on measures of effect and not biomarkers of effect, and is also protective of kidney cancer. If a TCE kidney toxicity value is derived based on our recommendations described here for a healthy worker population (*i.e.*, no UF_H or UF_A, and use of an HEC_{50} instead of an HEC_{99}), the TCE toxicity value would be much higher than the overly conservative toxicity value US EPA used in its risk evaluation to calculate risks for industrial processing aid workers.

It is noteworthy that US EPA's TCE non-cancer kidney toxicity value is based on metabolism through the GSH pathway and not on total metabolism that includes both the GSH and oxidative metabolic pathways (US EPA, 2011b). The HEC_{50} based on total metabolism is approximately 100-fold higher than the HEC_{50} based on the GSH pathway. Further, there is considerable uncertainty associated with the TCE PBPK model (Chiu *et al.*, 2009) that US EPA used in derivation of its TCE toxicity values. The model is based primarily on data from the Lash *et al.* (1998, 1999a,b) studies that used an unreliable analytical method for quantifying TCE metabolic flux through the GSH pathway. Recently, Zhang *et al.* (2018) conducted a direct comparison of the analytical method used by Lash *et al.* (1998, 1999a,b) and more reliable methods, and reported that the method that Lash *et al.* (1998, 1999a,b) used likely overestimates the TCE metabolic flux through the GSH pathway as compared to the more reliable methods. Therefore, the non-cancer kidney toxicity value derived by US EPA (2011b) is likely overly conservative for both kidney non-cancer and cancer effects.

4.2 Toxicological Basis of Current OELs

As previously noted, currently, there is one regulatory and two non-regulatory OELs for TCE: the OSHA PEL, NIOSH REL, and ACGIH TLV. The regulatory OSHA PEL of 100 ppm for an 8-hour TWA was derived in 1975 and is based on a study of acute health effects in animals (OSHA, 1975). The NIOSH REL and ACGIH TLV are non-regulatory OELs. The NIOSH REL of 25 ppm for a 10-hour TWA was derived in 1978 and is based on potential neurological effects and cancer effects in humans (NIOSH, 1992). The ACGIH TLV of 10 ppm for an 8-hour TLV was derived in 2007 and is based on a study of neurological effects and kidney toxicity in humans (ACGIH, 2020).

5 Consideration of Personal Protective Equipment

The estimated exposure concentrations presented in Section 3 do not account for PPE use. [redacted] Therefore, Gradient conducted an additional exposure evaluation for ENTEK workers, which considers PPE use.

5.1 Estimated PBZ TCE Concentrations Assuming PPE

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5.2 Assumptions and Uncertainties

This exposure evaluation involves multiple steps and assumptions, which contribute inherent uncertainties that affect the final exposure estimates. Examples of the assumptions made and associated uncertainties for the exposure estimates are presented below.

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- [redacted]

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6 Conclusions and Recommendations

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References

Agency for Toxic Substances and Disease Registry (ATSDR). 2019. "Toxicological Profile for Trichloroethylene." 511p., June. Accessed at https://www.atsdr.cdc.gov/ToxProfiles/tp19.pdf.

American Conference of Governmental Industrial Hygienists (ACGIH). 2020. "2020 Guide to Occupational Exposure Values." American Conference of Governmental Industrial Hygienists (ACGIH), Cincinnati, OH. 280p.

[redacted]

ENTEK. 2021a. Letter Report and Attachments to K. McNamara (US EPA, Office of Chemical Safety and Pollution Prevention) re: ENTEK International LLC, Request for Section 6(g) exemption, TSCA Section 6(a) TCE Rulemaking, Docket No. EPA-HQ-OPPT-2020-0642. July 14.

[redacted]

Hosgood, HD III; Zhang, L; Tang, X; Vermeulen, R; Qiu, C; Shen, M; Smith, MT; Ge, Y; Ji, Z; Xiong, J; He, J; Reiss, B; Liu, S; Xie, Y; Guo, W; Galvan, N; Li, L; Hao, Z; Rothman, N; Huang, H; Lan, Q. 2012. "Decreased numbers of CD4(+) naive and effector memory T cells, and CD8(+) naive T cells, are associated with trichloroethylene exposure." *Front. Oncol.* 1:53. doi: 10.3389/fonc.2011.00053.

Keil, DE; Peden-Adams, MM; Wallace, S; Ruiz, P; Gilkeson, GS. 2009. "Assessment of trichloroethylene (TCE) exposure in murine strains genetically-prone and non-prone to develop autoimmune disease." *J. Environ. Sci. Health A Tox. Hazard. Subst. Environ. Eng.* 44(5):443-453. doi: 10.1080/10934520902719738.

Lan, Q; Zhang, L; Tang, X; Shen, M; Smith, MT; Qiu, C; Ge, Y; Ji, Z; Xiong, J; He, J; Reiss, B; Hao, Z; Liu, S; Xie, Y; Guo, W; Purdue, M; Galvan, N; Xin, KX; Hu, W; Freeman, LE; Blair, A; Li, L; Rothman, N; Vermeulen, R; Huang, H. 2010. "Occupational exposure to trichloroethylene is associated with a decline in lymphocyte subsets and soluble CD27 and CD30 markers." *Carcinogenesis* 31(9):1592-1596.

Lash, LH; Qian, W; Putt, DA; Jacobs, K; Elfarra, AA; Krause, RJ; Parker, JC. 1998. "Glutathione conjugation of trichloroethylene in rats and mice: sex-, species-, and tissue-dependent differences." *Drug Metab. Dispos.* 26(1):12-19.

Lash, LH; Putt, DA; Brashear, WT; Abbas, R; Parker, JC; Fisher, JW. 1999a. "Identification of S-(1,2-dichlorovinyl)glutathione in the blood of human volunteers exposed to trichloroethylene." *J. Toxicol. Environ. Health* 56(1):1-21.

Lash, LH; Lipscomb, JC; Putt, DA; Parker, JC. 1999b. "Glutathione conjugation of trichloroethylene in human liver and kidney: Kinetics and individual variation." *Drug Metab. Dispos.* 27(3):351-359.

Maltoni, C; Lefemine, G; Cotti, G. 1986. *Experimental Research on Trichloroethylene Carcinogenesis.* Princeton Scientific Publishing Co., Inc., Princeton, NJ. Archives of Research on Industrial Carcinogenesis: Volume 5, 393p.

National Institute for Occupational Safety and Health (NIOSH). 1992. "NIOSH Recommendations for Occupational Safety and Health: Compendium of Policy Documents and Statements." DHHS (NIOSH) Publication No. 92-100, 217p., January.

National Institute for Occupational Safety and Health (NIOSH). 2008. "Evaluation of Neurological Dysfunction among Workers Exposed to Trichloroethylene. Health Hazard Evaluation Report HETA 2004-0372-3054: Entek International, Lebanon, Oregon." HETA 2004-0372-3054, 48p., March.

Occupational Safety and Health Administration (OSHA). 1975. "Proposed Standard for Occupational Exposure to Trichloroethylene." *Fed. Reg.* 40:49032-49045. October 20. [SL 026870 - 83]

US Congress. 2016. "An act to modernize the Toxic Substances Control Act, and fur other purposes [Frank R. Lautenberg Chemical Safety for the 21st Century Act]." H.R. 2576. 66 p. June 22. Accessed at http://www.congress.gov/bill/114th-congress/house-bill/2576/text

US EPA. 2011a. "Recommended Use of Body Weight(3/4) as the Default Method in Derivation of the Oral Reference Dose (Final)." Risk Assessment Forum. EPA/100/R11/0001, 50p.

US EPA. 2011b. "Toxicological Review of Trichloroethylene (CAS No. 79-01-6) in Support of Summary Information on the Integrated Risk Information System (IRIS) (Final)." EPA/635/R-09/011F, 2469p., September. Accessed at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0199tr/0199tr.pdf.

US EPA. 2020. "Risk Evaluation for Trichloroethylene (CASRN: 79-01-6) (Final)." Office of Chemical Safety and Pollution Prevention. EPA Document # 740R18008, 803p., November. Accessed at https://www.epa.gov/sites/production/files/2020-11/documents/1._risk_evaluation_for_trichloroethylene_tce_casrn_79-01-6.pdf.

[redacted]

Zhang, L; Bassig, BA; Mora, JL; Vermeulen, R; Ge, Y; Curry, JD; Hu, W; Shen, M; Qiu, C; Ji, Z; Reiss, B; McHale, CM; Liu, S; Guo, W; Purdue, MP; Yue, F; Li, L; Smith, MT; Huang, H; Tang, X; Rothman, N; Lan, Q. 2013. "Alterations in serum immunoglobulin levels in workers occupationally exposed to trichloroethylene." *Carcinogenesis* 34(4):799-802. doi: 10.1093/carcin/bgs403.

Zhang, F; Marty, S; Budinsky, R; Bartels, M; Pottenger, LH; Bus, J; Bevan, C; Erskine, T; Clark, A; Holzheuer, B; Markham, D. 2018. "Analytical methods impact estimates of trichloroethylene's glutathione conjugation and risk assessment." *Toxicol. Lett.* 296:82-94. doi: 10.1016/j.toxlet.2018.07.006.