OTNE CONSORTIUM

Managed by B&C® Consortia Management, L.L.C.

November 16, 2020

Via Central Data Exchange

Ms. Bethany A. Masten
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Request for Risk Evaluation under the Toxic Substances Control Act; Octahydro-Tetramethyl-Naphthalenyl-Ethanone Chemical Category

Dear Ms. Masten:

Pursuant to Section 6(b)(4)(C)(ii) of the Toxic Substances Control Act (TSCA) and 40 C.F.R. Section 702.37, International Flavors and Fragrances, Inc. (IFF), Privi Organics USA Corporation (Privi), and DRT America, Inc. (DRT) (submitting entities), through the OTNE Consortium, formally request that the U.S. Environmental Protection Agency (EPA) conduct a risk evaluation of octahydro-tetramethyl-naphthalenyl-ethanone (OTNE). B&C® Consortia Management, L.L.C. (BCCM), as the manager of the OTNE Consortium, of which IFF, Privi, and DRT are members, is pleased to submit this manufacturer request. Although there are other members of the OTNE Consortium, this request is submitted on behalf of only the aforementioned submitting entities. This document and Appendices I through VII provide the information set forth in 40 C.F.R. Section 702.37(b). This amended submission reflects the changes and additional information requested by EPA.

Background

The OTNE Consortium includes major manufacturers, importers, and users of OTNE. For OTNE Consortium purposes, "OTNE" is identified as a category of chemical substances consisting of four inseparable individual isomers: ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl), ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), and ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)

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with Chemical Abstracts Service (CAS) Registry Numbers (RN) 54464-59-4, 54464-57-2, 68155-67-9, and 68155-66-8, respectively. The OTNE Consortium advocates on behalf of member company interests.

Contact Information of Entity Submitting the Request

The submitting entities request that all questions or requests for additional information be directed to the OTNE Consortium Manager, Heather J. Blankinship, at (202) 557-3800 or hblankinship@bc-cm.com. The contact information required pursuant to 40 C.F.R. Section 702.37(b)(1) for the submitting entities listed above is provided in Appendix I.

Substance Identity

The chemical identity of OTNE is provided in Appendix II. The four isomers in OTNE are manufactured together, are very similar in molecular structure, in physicochemical and biological properties, in use, and in mode of entrance into the human body and the environment, and therefore, they should be considered a chemical category. In a 2018 letter from Dr. Jeffery T. Morris to Dr. Xing Han, EPA agreed to treat the four isomers of OTNE as a category of chemical substances under 15 U.S.C. Section 2625(c) and to prepare a single risk evaluation.[1]

Information Relevant to Conditions of Use and Exposure

The submitting entities, through the OTNE Consortium, request that the following uses be evaluated under the risk evaluation of OTNE:

- OTNE manufacturing; and
- OTNE used as a fragrance ingredient in consumer products.

The rationale for the request of these uses is based on the information available from the Chemical Data Reporting (CDR) database and past industry surveys. These categories correspond to activities and uses reported by industry for the 2016 TSCA CDR and two surveys regarding uses of OTNE in consumer products. As such, they represent circumstances under which OTNE is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of," and therefore, constitute conditions of use under

[1] Letter from Jeffery T. Morris, Ph.D., Director, Office of Pollution Prevention and Toxics (OPPT), to Xing Han, Ph.D., DABT, Regulatory Director, Toxicology and Risk Assessment, Global Regulatory Affairs, IFF (Dec. 20, 2018).

40 C.F.R. Section 702.33. Appendix III provides the specific categories and subcategories of the conditions of use that comprise the uses requested for inclusion. Available information and a further explanation of the basis for the specified conditions of use and references for the cited reports are provided in Appendices III through V.

Information Regarding the Chemical Substance's Hazard and Exposure Potential, Persistence, and Bioaccumulation

The hazard and exposure potential, persistence, and bioaccumulation of the chemical substance is provided in Appendices III through V. Study reports cited in the Reference section of the Appendices that are not publicly available are also included with this risk evaluation request. These data were gathered in a manner consistent with EPA's goal of "high-quality, fit-for-purpose risk evaluations that rely on the best available science and the weight of the scientific evidence within the context of TSCA."[2]

Potentially Exposed or Susceptible Subpopulations That the Manufacturer(s) Believe to Be Relevant to the EPA Risk Evaluation

Potentially exposed or susceptible subpopulations are expected to include infants, children, pregnant women, workers, and the elderly, given the potential for use of OTNE as a fragrance in consumer products such as bath and shower products, personal care products, and laundry products such as fabric softeners and detergents. Additional information regarding exposures is included in Appendix III.

Production Volume or Significant Changes in Production Volume

Information regarding trends in production volume and volumes of use survey is provided in Appendix III.

Potential for Storage of Chemical Substance near Significant Sources of Drinking Water, Including Storage Facility Location and Nearby Drinking Water Source(s)

The substance is a common component of numerous fragrance formulations and is used in numerous fragrance compounding facilities and consumer product manufacturing facilities across the United States. Storage of OTNE occurs at manufacturing and process sites, where it is stored indoors in structurally sound, non-leaking tanks and containers.

[2] EPA, Office of Chemical Safety and Pollution Prevention, *Application of Systematic Review in TSCA Risk Evaluations*, EPA Document 740-P1-8001 (May 2018).

The physicochemical properties of OTNE and its fate and behavior in environmental media have been evaluated in several studies cited in Appendix VI. OTNE has a high measured octanol-water partitioning coefficient (Log K_{ow} =5.65) and a high modeled octanol-carbon partitioning coefficient (EPISUITE Log K_{oc} = 4.24, extrapolated from Log K_{ow}) and low water solubility (2.68 mg/L at 20 °C) that indicates it preferentially absorbs to organic matter in sediments and soils. OTNE has been evaluated in a soil dissipation field study that indicates it does not leach through the soil column, and therefore it is not mobile and is unlikely to reach groundwater sources. Its measured high rate of degradation in soil (DT_{50} = < 6 days), water (DT_{50} = < 1 day), sediment (DT_{50} = 9.2 days), and air (DT_{50} = < 1 hour) further support that OTNE is not persistent and not able to be transported long distances. Given the physicochemical properties of OTNE, and the evidence that supports OTNE is rapidly degraded and not mobile in environmental field studies and simulation tests, the potential for OTNE contamination of drinking water is low. Relevant information is also included in Appendix VI.

To fulfill the requirement of 40 C.F.R. Section 702.37(b)(4)(iv), Appendix VII includes information regarding storage of neat OTNE near significant sources of drinking water, including storage facility locations and nearby drinking water sources.

The data summarized above and in the Appendices and study reports that are not publicly available, which are submitted with this request, include information regarding physicochemical properties, conditions of use, environmental fate, engineering, and exposure, as well as human health and environmental hazards. It is the submitting entities' view that these data are adequate to permit EPA to complete a risk evaluation addressing the circumstances identified in this request for a risk evaluation.

Commitment to Provide Any Referenced Information upon Request

To fulfill the requirement of 40 C.F.R. Section 702.37(b)(5), a signed commitment is provided in Appendix I for each of the submitting entities.

Addendum

The submitting entities, through the OTNE Consortium, believe that, to the best of their knowledge, they have provided to EPA all the currently existing available information that is relevant to the risk evaluation of OTNE.

Efforts are being made to acquire additional hazard and/or exposure-related information for OTNE, which will be made available to EPA for the purpose of this risk evaluation if and when such information has been gathered.

The studies listed in the Reference section of this request that cite the Research Institute for Fragrance Materials, Inc. (RIFM) as the source are the property of RIFM. The submitting entities have written permission from RIFM for the express purpose of submitting the studies to EPA to support this manufacturer-requested risk evaluation. The posting of these documents to a public docket maintained by a governmental agency is not a waiver of ownership rights of RIFM. Any use of the documents by any other person without express written permission would constitute a violation of RIFM's rights and subject that person to civil liability.

The studies in the Reference section of this request that cite IFF as the source and are submitted with this request are owned in whole or in part by IFF and are proprietary. If these study reports are disclosed in their entirety, the test sponsors would suffer significant economic losses. IFF has redacted certain information from the studies to protect the proprietary and confidential business information (CBI) of the study owners. The level of disclosure provided in the redacted study reports is adequate to allow the public to assess the health and safety data and to evaluate the quality of the studies without identifying proprietary information that could allow competitors to use illegitimately the studies to register their products in other countries.

The submitting entities believe that TSCA provides EPA with authority to provide this protection. First, Section 14(b)(2) of TSCA gives EPA the discretion to disclose health and safety studies -- it "does not prohibit the[ir] disclosure," rather than mandating it.[3] Second, EPA's regulations on confidentiality and public access to information in connection with new chemicals have long allowed EPA to uphold a claim of confidentiality for chemical identity when "[t]he specific chemical identity is not necessary to interpret a health and safety study."[4] In this case, IFF is not seeking protection for chemical identity. Instead, it is seeking protection of non-controversial information that is not necessary to interpret health and safety data but is relevant primarily to an entity's ability to protect key information required to claim ownership or to submit the study reports in support of a chemical registration in another country. These data include elements entirely unrelated to the study results such as the study date, the laboratory name, the laboratory project number, and the names and signatures of researchers. As we have discussed, it is our view that these redactions protect the owners' intellectual property while providing sufficient transparency to the public to evaluate the outcome of the studies.

Certification

To fulfill the requirement of 40 C.F.R. Section 702.37(b)(7), a signed certification is provided in Appendix I for each of the submitting entities.

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3 15 U.S.C. § 2613(b)(2).

4 40 C.F.R. § 720.90(c)(3).

The OTNE Consortium appreciates the opportunity to submit this request for a risk evaluation. If you have any questions or requests for additional information, please contact me at (202) 557-3800 or hblankinship@bc-cm.com.

Sincerely,

Heather J. Blankinship

Heather J. Blankinship
OTNE Consortium Manager

Attachments

Appendix I. Certification, Commitment, and Contact Information of the Submitting Entities.

Please see the following pages.

Re: Certification, Commitment, and Contact Information of the Submitting Entity Request for Risk Evaluation under the Toxic Substance, Octahydro-Tetramethyl-Naphthalenyl-Ethanone (OTNE) Chemical Category

Commitment to provide any referenced information upon request per 40 C.F.R. Section 702.37(b)(5):

Privi Organics USA Corp., through B&C® Consortia Management, L.L.C. (BCCM), hereby commits to provide to EPA any referenced information upon request.

Certification of Manufacturer-Requested Risk Evaluation:

I certify that to the best of my knowledge and belief:

Privi Organics USA Corp. imports the chemical substances identified for risk evaluation.

All information provided in the "Re: Request for Risk Evaluation under the Toxic Substances Control Act; Octahydro-Tetramethyl-Naphthalenyl-Ethanone (OTNE) Chemical Category" is complete and accurate as of the date of the request.

I have either identified or am submitting all information in my possession, control, and a description of all other data known to or reasonably ascertainable by me as required for this request under this part, 40 C.F.R. Part 702. I am aware it is unlawful to knowingly submit incomplete, false, and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

As required by 40 C.F.R. Section 702.37(b)(1), I am providing the following information:

Privi Organics USA Corp.
51 Distribution Blvd,
Edison, New Jersey 08817,
United States
Company contact name: Raj Doppalapudi
Contact phone number: Phone: +001 7329604513

Sincerely,

Raj Doppalapudi , Country Head

11/05/2020
Date

{01615.002 / 111 / 00306336.DOC 6}

DRT
the Best for Nature

A Company of the Firmenich Group

DRT America Inc.
400 Governor Treutlen Drive
Rincon, Georgia, USA 31326
Tel + 1 912-223-2079

philippe.saintecluque@drtamerica.com
http://www.drt.fr

Philippe SAINTE-CLUQUE
President DRT America Inc.

Re: Certification, Commitment, and Contact Information of the Submitting Entity Request for Risk Evaluation under the Toxic Substance, Octahydro-Tetramethyl-Naphthlenyl-Ethanone (OTNE) Chemical Category

Commitment to provide any referenced information upon request per 40 C.F.R. Section 702.37(b)(5):

DRT America Inc through B&C® Consortia Management, L.L.C. (BCCM), hereby commits to provide to EPA any referenced information upon request.

Certification of Manufacturer-Requested Risk Evaluation:
I certify that to the best of my knowledge and belief:

DRT America Inc manufactures and/or imports the chemical substances identified for risk evaluation.

All information provided in the "Re: Request for Risk Evaluation under the Toxic Substances Control Act; Octahydro-Tetramethyl-Naphthlenyl-Ethanone (OTNE) Chemical Category" is complete and accurate as of the date of the request.

I have either identified or am submitting all information in my possession, control, and a description of all other data known to or reasonably ascertainable by me as required for this request under this part, 40 C.F.R. Part 702. I am aware it is unlawful to knowingly submit incomplete, false, and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

As required by 40 C.F.R. Section 702.37(b)(1), I am providing the following information:

DRT America Inc
400 Governor Treutlen Drive
Rincon, Georgia, 31326
Philippe Sainte-Cluque, 912-223-2079

Sincerely,

Philippe Sainte-Cluque, President DRT America Inc

November 6, 2020

Cc: Conrad Shannon – Regulatory Affairs Senior Manager

Re: Certification, Commitment, and Contact Information of the Submitting Entity Request for Risk Evaluation under the Toxic Substance, Octahydro-Tetramethyl-Naphthlenyl-Ethanone (OTNE) Chemical Category

Commitment to provide any referenced information upon request per 40 C.F.R. Section 702.37(b)(5):

International Flavors & Fragrances Inc (IFF), through B&C® Consortia Management, L.L.C. (BCCM), hereby commits to provide to EPA any referenced information upon request.

Certification of Manufacturer-Requested Risk Evaluation:

I certify that to the best of my knowledge and belief:

IFF manufactures and/or imports the chemical substances identified for risk evaluation.

All information provided in the "Re: Request for Risk Evaluation under the Toxic Substances Control Act; Octahydro-Tetramethyl-Naphthlenyl-Ethanone (OTNE) Chemical Category" is complete and accurate as of the date of the request.

I have either identified or am submitting all information in my possession, control, and a description of all other data known to or reasonably ascertainable by me as required for this request under this part, 40 C.F.R. Part 702. I am aware it is unlawful to knowingly submit incomplete, false, and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

As required by 40 C.F.R. Section 702.37(b)(1), I am providing the following information:

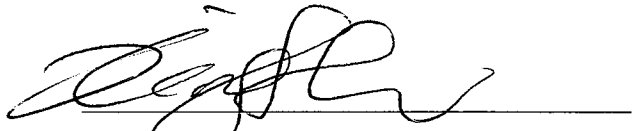
International Flavors & Fragrances Inc.
521 West 57th Street
New York, NY 10019
United States

iff.com

Company contact name: Xing Han

Contact phone number: 732-203-8139 (office)

Sincerely,



11/5/2020

Xing Han **Date**

Vice President

Toxicology and Risk Assessment

Global Regulatory Affairs

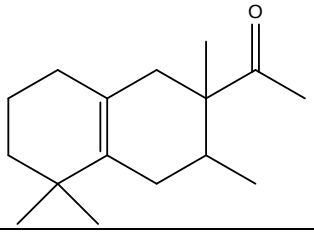
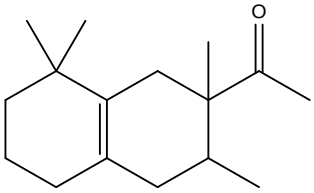
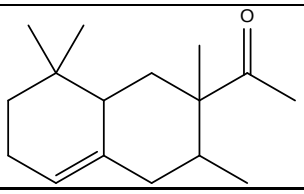
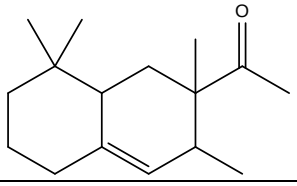
IFF

Appendix II. Substance Identity.

OTNE is a commercial product that is composed of four inseparable isomers and is manufactured, imported, and processed as a single chemical product. The four isomers in OTNE, Chemical Abstracts Service (CAS) Registry Numbers (RN) 54464-59-4, 54464-57-2, 68155-67-9, and 68155-66-8, are similar in molecular structure, in physical, chemical, and biological properties, in use, and in mode of entrance into the human body and the environment, and therefore they should be considered a chemical category for purposes of risk evaluation. In a letter from Dr. Jeffery T. Morris, Director, U.S. Environmental Protection Agency (EPA), Office of Pollution Prevention and Toxics (OPPT), to Dr. Xing Han, International Flavors & Fragrances, Inc. (IFF), Vice President, Global Regulatory Affairs, on December 20, 2018, EPA agreed to treat the four isomers of OTNE as a category of chemical substances under 15 U.S.C. Section 2625(c) and to prepare a single risk evaluation.

In the U.S., for Toxic Substances Control Act (TSCA) purposes, the OTNE product is identified as four isomers. Test reports may specify the four isomers as the test substance or only a representative isomer.

The identity of OTNE is described in the table below:

CAS RN	Chemical Name	Structure Formula	Weight Range (%)
54464-59-4	Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl)-		0 – 5
54464-57-2	Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)-		30 – 65
68155-67-9	Ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)-		8 – 20
68155-66-8	Ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)-		10 – 33

Molecular formula: $C_{16}H_{26}O$
Molecular weight: 234.377

The same product is identified in the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program as Reaction Mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-

naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one, with European Community (EC) number 915-730-3.

Other common or trade names of OTNEs are:

2-Acetyloctahydro-2,3,8,8-tetramethylnaphthalene
Amber Fleur
Amber Gamma
Ambergris Ketone
Amberian
Ambralux
Amberonne
Anthamber
Boisvelone
Hamber
Hamber premium
Iso Ambois
Iso Ambois Super
Isocyclemone E
Iso E Super
Iso Gamma Super
Iso Velvetone
Orbitone
Orbitone T
Tetramethyl acetyloctahydronaphthalenes

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 2 0 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dr. Xing Han, Ph.D., DABT
Regulatory Director, Toxicology and Risk Assessment
Global Regulatory Affairs
International Flavors and Fragrances, Inc.
800 Rose Lane
Union Beach, NJ 07735

Dear Dr. Han:

Thank you for the recent discussions with the Office of Pollution Prevention and Toxics regarding procedures around submitting an amended request for a manufacturer-requested risk evaluation for the chemicals commonly known as ethanones, or OTNEs, that are on the TSCA Work Plan for Chemical Assessments: 2014 Update. I am writing to address the specific questions outlined in your emails dated November 7 and November 26, 2018.

By way of history, in a letter dated September 28, 2016, EPA explained the requirements for submitting a manufacturer-requested risk evaluation, and determined that two of the ethanones: 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), CAS No. 68155-67-9 and 1-(1,2,3,5,6,7,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), CAS No. 68155-66-8, are not subject to section 6(h) of the Toxic Substances Control Act (TSCA). The agency also confirmed that the other two ethanones: 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl) CAS No. 5446459-4, and 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), CAS No. 54464-57-2, met the initial requirements for a manufacturer-requested risk evaluation, and would be excluded from the expedited actions under section 6(h) of TSCA. EPA also explained in the letter that before manufacturer-requested risk evaluations could proceed, final rules would need to be promulgated for risk evaluation and the collection of fees. Both these rules have now been promulgated.

Regarding your specific questions, in reviewing the four isomers for risk evaluation and collection of fees, should you submit an amended request, we will treat the four isomers noted above as a "category of chemical substances" under 15 U.S.C. § 2625(c) and prepare a single risk evaluation. Because a single risk evaluation would be prepared for this category, a single fee would be assessed and required to be paid after review of the manufacturer-requested risk evaluation is completed by EPA and EPA grants the request. This is expected to occur approximately six to eight months after submittal of the request.

As agreed through various conference calls throughout the fall, EPA is requesting that the International Flavors and Fragrances, Inc. (IFF) alone, or as part of an industry consortium, submit an amended manufacturer-requested risk evaluation to include all four isomers as a chemical category. Once EPA receives the amended request, EPA can begin to evaluate the chemical category in a single risk evaluation. This risk evaluation for the four isomers will not be subject to the expedited procedures under section 6(h). For additional details on the exact processes that will be followed in risk evaluation and collection of fees, please consult the final risk evaluation rule we shared with you for a more detailed description of the processes for both actions. If you have further questions regarding these processes, please let us know.

I also understand there is agreement that the amended request for a risk evaluation for the four isomers will be submitted in May 2019. This date allows EPA to initiate the risk evaluation procedures in a timely manner, while considering the new studies (which we understand are either underway or will be underway shortly) that IFF and its international consortium have undertaken for the ECHA process.

Thank you for the productive discussions, and we look forward to your response. If you have further questions, or would like to organize a conference call, please contact Joel Wolf at 202-564-0432, or wolf.joel@epa.gov.

Sincerely,

Jeffery T. Morris, Ph.D.
Director
Office of Pollution Prevention and Toxics

Appendix III. Information Relevant to Conditions of Use and Exposure.

1. Manufacturing/Import

Manufacturing and importing volumes of OTNE and its isomers are available via the EPA's Chemical Data Reporting (CDR) database. The 2015 CDR database reports that production volumes have remained constant from 2012-2014 but have increased in 2015:

Reporting Year		**2012**	**2013**	**2014**	**2015**
National Aggregate Production Volume (lbs) by CAS RN	54464-57-2	1-10,000,000	1-10,000,000	1-10,000,000	10,000,000-50,000,000
	68155-67-9	1-10,000,000	1-10,000,000	1-10,000,000	10,000,000-50,000,000
	68155-66-8	1-10,000,000	1-10,000,000	1-10,000,000	10,000,000-50,000,000
	54464-59-4	< 25,000	< 25,000	< 25,000	25,000-100,000

Since OTNE is an inseparable mixture, the aggregate volume of 10,000,000 to 50,000,000 pounds for 2015 represents the aggregate volume of all the isomers combined.

2. Volumes of Use Survey

The Research Institute for Fragrance Materials (RIFM) and the International Fragrance Association (IFRA) surveyed IFRA members to compile a global, sector-wide picture of OTNE used (Volume of Use, VoU) by IFRA members. The VoU survey of OTNE indicates that the volume used in the U.S. for the years 2000, 2004, and 2008 showed a volume of 760, 1186, and 1869 U.S. tons, respectively. For 2011 and 2015 (2015 being the latest year surveyed), the VoU was surveyed for North America, and the figures were 2553 and 4066 U.S. tons, respectively.

3. Consumer Product Uses

3.1 In 2001, the results of an industry survey were published by Royal Haskoning and RIFM illustrated the percent distribution of fragrance oils consumed in the EU by product category (EN25). The results are reproduced below. While this survey was performed in 2001, the results are not expected to change significantly. Provided that OTNE is a high-volume fragrance ingredient, the industry anticipates that the distribution of the use of OTNE is reflective to that of fragrance oils in general where the highest volume is used in bath and shower products, personal care products, and laundry products such as fabric softeners and detergents.

Product category where fragrance oils are used	**Distribution of fragrance oil usage (%)**	**Reference**
Detergent	25	EN25
Fabric softeners	14	

Personal care	13	
Bath and shower	10	
Hair care	10	
Soaps	9	
Industrial and household cleaner	8	
Other	6	
Fine Fragrances	5	

3.2 The use levels of OTNE as a fragrance ingredient in cosmetic and consumer products have been surveyed by RIFM. The column labeled as "95th Percentile Concentration (%) in Final Products" in the table below shows the survey results using three CAS RNs (54464-57-2, 68155-66-8, and 68155-67-9) to represent OTNE.

Aggregated Consumer Exposure	
1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone	
CAS RN 54464-57-2	**RIFM Concentration Survey No. 019, 2018**
CAS RN 68155-66-8	**RIFM Concentration Survey No. 014, 2017**
CAS RN 68155-67-9	**RIFM Concentration Survey No. 014, 2017**
Product Category	95th Percentile Concentration (%) in Final Products[1]
Category 1 - Products applied to the lips (lipstick)	0.048
Category 2 - Products applied to the axillae	0.59
Category 3 - Products applied to the face/body using finger tips	0.045
Category 4 - Products related to fine fragrances	

	4.5
Category 5A - Body Lotion products applied to the face and body using the hands (palms), primarily leave-on	0.56
Category 5B - Face Moisturizer products applied to the face and body using the hands (palms), primarily leave-on	0.053
Category 5C - Hand Cream products applied to the face and body using the hands (palms), primarily leave-on	0.080
Category 5D - Baby Cream, Oil, Talc	No Data
Category 6 - Products with oral and lip exposure	0.00
Category 7 - Products applied to the hair with some hand contact	0.072
Category 8 - Products with significant ano-genital exposure (tampon)	No Data
Category 9 - Products with body and hand exposure, primarily rinse off (bar soap)	0.24
Category 10A - Household Care products with mostly hand contact (hand dishwashing detergent)	No Data
Category 10B - Aerosol Air Freshener	0.61
Category 11 - Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate (Feminine hygiene pad)	No Data

Category 12 - Other Air Care Products not intended for direct skin contact, minimal or insignificant transfer to skin	21
[1]Highest 95th percentile concentration reported for all three CAS RNs associated with the material.	

4. Release and Waste Disposal via Waste Water Treatment Plant (WWTP) and Environmental Exposure

4.1 Industry emission values to waste water

Process	**Facility size**	**Product type**	**% Released to waste water**	**Reference**
Compounding	Large/Medium	Fragrance oil/compound	0.2%	EN24
	Small		0.5%	
Blending/Formulating Finished Products Containing Fragrance Oil	Large	Hard Soaps/Soap Bar	0.05%	
	Large	Granular Detergents	0.1%	
	Large	Liquid cleaners, conditioners, shampoos and shower gels	0.1%	
	Small		0.2%	
	Generic	Liquid Creams and Lotions	1%	
	Generic	Fine fragrances and perfume products	0-1.5%, 0% if alcohol is used for cleaning	

4.2 Field and lab measured waste water treatment removal efficiencies

Sample origin/method	**Removal % (avg. ± standard deviation)**	**Reference**
U.S. - Activated sludge waste water treatment	59.2 ± 11.4%, primary treatment; 96.8 ± 1.5%, primary + secondary treatment	EN23
U.S. - Trickling filter waste water treatment	43%, primary treatment; 89.7%, primary + secondary treatment	
Effluent	91.7 ± 10%	EN22
Activated sludge simulation	89% based on parent compound	EN05

study with radiolabeled OTNE	with remaining radioactivity lost due to mineralization, volatile loss, and sorption	

4.3 Measured concentrations in United States (U.S.) waste water effluent and sludge

Sample origin	**Concentration**	**Reference**
Effluent from 44 U.S. WWTPs	Average of 44 samples, 0.69 ± 0.65 µg/L (Range: 0.02-2.61); 50th percentile, 0.47 and 90th percentile, 1.58 µg/L	EN21
Sludge from 44 U.S. WWTPs	Average of 44 samples, 20.6 ± 33.6 mg/kg dry weight sludge (Range: 0.73-212); 50th percentile, 9.15 and 90th percentile, 50.7 mg/kg dry weight sludge	
Effluent from 12 U.S. WWTPs	0.028- 0.672 µg/L	EN22
Anaerobically digested and dewatered sludge from 2 U.S. WWTPs	7.3 and 30.7 mg/kg dry weight sludge	EN24

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Appendix IV. Typical Practices of OTNE Manufacturing, Packaging and Quality Control Operations.

OTNE manufacturing site location
IFF Chemical Holdings, Inc.
2051 N. Lane Avenue
Jacksonville, FL 32254

The manufacturing and processing of OTNE (liquid) consists of five general steps: 1. Reaction; 2. Refinement; 3. Purification; 4. Storage; and 5. Packaging. The manufacturing site operates under an open-air configuration and the reaction, refinement and purification steps take place in closed vessels thus minimizing worker exposure.

Supervisors remotely operate the site with floor operators in the vicinity to confirm operations and conduct quality control (QC) sampling. To ensure OTNE quality, at each step, workers take QC samples:

1. Reaction → QC sample to verify reaction completion
2. Refinement → QC sample to verify wash completion
3. Purification → QC sample to verify purity achieved
4. Storage → QC sample to verify quality prior to packaging
5. Packaging → QC sample to verify quality prior to shipping

[redacted]

Workers package OTNE on an as needed basis and therefore packaging is sporadic throughout the year. [redacted]

To maintain quality, as indicated, workers sample OTNE throughout the process. [redacted]

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Table 1 lists the activities where worker exposure to OTNE potentially occurs. Exposures were anticipated to occur only via inhalation due to the personal protection equipment (PPE) used and/or the nature of the activities. The estimated exposure time factors in the duration and frequency of the activity in a given day. The estimated number of days of exposure depends on the frequency the activity occurs in the course of a given work year (*e.g.*, activity happens 75 out of the 250 day work year). The activities listed below correspond to OTNE manufacturing and processing outlined above:

Table 1. Potential approximate worker inhalation exposure per typical activity

Activity	**Location and estimated ventilation rate[1]**	**Estimated exposure time (hours/site-day)[2]**	**Estimated number of days of exposure (days/site-yr)[3]**	**Number of Workers**	**Predicted average daily dose (mg/kg-day)[4]**	**PPE[5]**
QC sampling of liquid material production	Outdoor/open air configura-tion; ventilation rate of 26,400 ft^3/min	<0.1	75	1	3.34E-07	Chemical resistant gloves, safety glasses, hard hat, safety shoes
QC sampling of liquid material during refining		<0.06	75	1	2.00E-07	
QC sampling of liquid material during purification		<0.2	75	1	6.68E-07	
QC sampling of liquid material prior to storage		<0.06	250	1	6.68E-07	
QC sampling of liquid material during storage		<0.03	250	1	3.34E-07	
QC sampling of liquid material during packaging of tank truck/ISO tanker		<0.08	250	1	1.39E-05	

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QC sampling of liquid material during packaging of totes and drums		<0.03	30	1	4.87E-07	
Packaging of 260 gallon totes		~1.0	5 - 20	1	6.411E-05	
Packaging of 55 gallon drums		~3.3	5 - 20	1	7.32E-05	Safety glasses, hard hat, safety shoes; no gloves used as there is no contact with liquid OTNE [redacted]

[1]The OTNE manufacturing site operates as an open-air configuration, therefore, all activities listed take place in open air. The estimated ventilation rate is based on an open-air configuration with worst-case scenario wind speed of 1 mph calculated per EPA ChemSTEER guidance.

[2]Estimated potential worker exposure time based on the total time it takes to sample or package liquid OTNE in one day. Examples include the estimated time it takes to open sampling valve, sample, and close valve or the time it takes to package one drum or tote. The estimated time it takes to sample or package is then multiplied by the frequency of the activity estimated to be typical for a given day. This yields the total estimated worker exposure time in column three.

[3]Estimated number of days the activity occurs for a worker who works 250 days per year. For activities listed as occurring 75 days of the 250 day work year, the number of days reported are based on the activity occurring estimated 30% of the time, as not all steps of the manufacturing process occur every day. To estimate the number of days the activity takes place for drum and tote packaging, the estimated total number of drums or totes packaged per year is divided by the typical number packaged in a given day.

[4]Predicted average daily doses for identified worker inhalation exposure scenarios were estimated using EPA ChemSTEER and the measured physical and chemical properties of OTNE (*i.e.*, vapor pressure, molecular weight, density and solubility). To estimate the vapor generation rate from sampling liquid OTNE, the EPA/OPPT Mass Transfer Coefficient Model was used with parameters set conservatively (*e.g.*, High end diameter of opening/pool (10cm)). To estimate the vapor generation rate from packaging liquid OTNE in drums and totes, the EPA/Office of Air Quality Planning and Standards (OAQPS) AP-42 Loading Model was used with parameters set conservatively if parameters could not be refined (*e.g.*, Worst case saturation factor (1)). Finally, to predict average daily dose, for both sampling and packaging liquid OTNE, the EPA/OPPT Mass Balance Model was used. Here, worst case values were used

for parameters that could not be refined (*e.g.*, Worst case mixing factor (0.1)). The estimated ventilation rate, estimated worker exposure time and number of days of exposure were based on information obtained from the site, listed in Table 1.

[5]PPE typically used during sampling or packaging of OTNE. Due to the use of PPE, dermal exposure is expected to be negligible.

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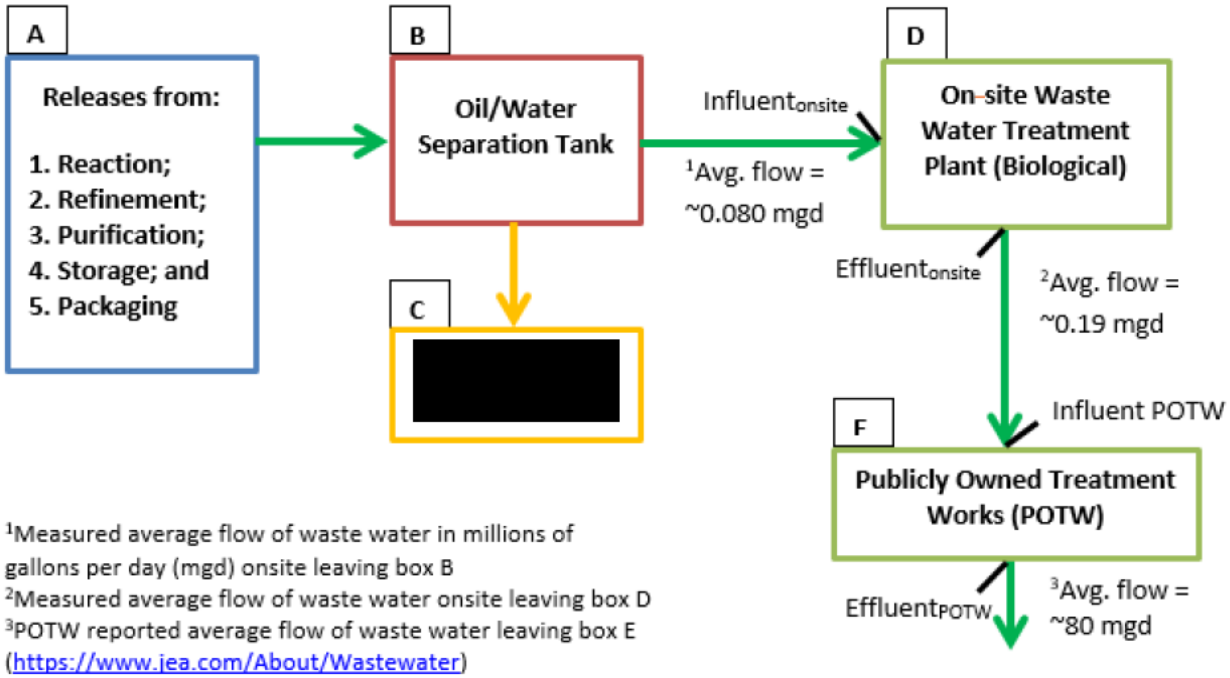
Appendix V. Typical Engineering Controls to Mitigate Releases of OTNE from Manufacturing and Processing.

OTNE manufacturing site location
IFF Chemical Holdings, Inc.
2051 N. Lane Avenue
Jacksonville, FL 32254

During the manufacturing and processing of OTNE (liquid), potential releases to waste water occur under a few identified scenarios:

- Cleaning reaction vessels, wash tanks and holding tanks (est. ~1 time a year, as needed);
- Refinement and purification of OTNE as wash waters and condensate from the distillation columns contain some residual OTNE oils; and
- Cleaning dedicated filling lines used in transferring OTNE to drums, totes, and material storage tanks.

While releases from these activities may occur periodically, several engineering controls mitigate the final release of OTNE to waste water effluent. The process diagram below highlights the engineering controls involved in OTNE release mitigation:



[1]Measured average flow of waste water in millions of gallons per day (mgd) onsite leaving box B
[2]Measured average flow of waste water onsite leaving box D
[3]POTW reported average flow of waste water leaving box E
(https://www.jea.com/About/Wastewater)

As highlighted in the figure above, released OTNE (box A) enters the Oil/Water Separation Tank (box B). The Oil/Water Separation Tank physically separates out residual OTNE from water by differences in their density. [redacted]

[redacted] This step employs a biological treatment process that can be described as a below grade lined basin. Microbes degrade the dissolved OTNE, thereby reducing the amount released to the local municipal WWTP, POTW (box E). These same processes are applicable for removal of OTNE at the POTW, as the POTW uses a secondary biological treatment system, filtration and clarifiers to improve water quality.

To estimate the concentration of OTNE in waste water effluent released from the POTW to local surface waters, a few conservative assumptions and measured data were considered using a mass-balance approach:

- Conservative assumption that OTNE is present in waste water leaving the Oil/Water Separation Tank (box B) at the limit of its measured water solubility of 2.68 mg/L;[1]
- The concentration of OTNE in waste water is diluted by additional onsite waste water flows and flows reported by the POTW; and
- The concentration of OTNE in waste water effluent is reduced 90% via waste water treatment as ~90% removal is indicated by EPISUITE STP modeling and measured data in supporting waste water simulation and field studies.[2,3]

Based on the available information and assumptions, the calculated concentration in the POTW effluent, not considering in-stream dilution, is 0.000032 mg/L or 32 parts per trillion. The mass balance calculations used to predict the concentration of OTNE in the POTW effluent are provided below.

1. Assuming OTNE is present in waste water at the limit of its water solubility,[1] the onsite waste water influent concentration is calculated considering dilution from combined waste water flow:
   - Conc. OTNE $\text{Influent}_{\text{onsite}}$ = 2.68 mg/L ÷ 2.375 (Dilution factor from combining flows from box D and B, respectively, or 0.19 mgd ÷ 0.08 mgd)
   - Conc. OTNE $\text{Influent}_{\text{onsite}}$ = 1.34 mg/L

2. To determine the effluent leaving the onsite treatment plant, box D, the measured removal rate of 90% from supporting studies and EPISUITE STP modeling is applied:[2,3]
   - Conc. OTNE $\text{Effluent}_{\text{onsite}}$ = 1.34 mg/L * 0.1 (fraction remaining after 90% removal)
   - Conc. OTNE $\text{Effluent}_{\text{onsite}}$ = 0.134 mg/L

3. Next, the POTW influent concentration is calculated by taking the effluent leaving the onsite WWTP, from box D, and applying a dilution factor as the flows leaving the onsite facility are combined with additional flows from the POTW:
   - Conc. OTNE $\text{Influent}_{\text{POTW}}$ = 0.134 mg/L (conc. from $\text{effluent}_{\text{onsite}}$) ÷ 421 (Dilution factor from combining flows from box E and box D, respectively, or 80 mgd ÷ 0.19 mgd)

[1] PC06. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – Water Solubility

[2] EN22. Simonich SL, Federle TW, Eckhoff WS, Rottiers A, Webb S, Sabaliunas D, de Wolf W. Removal of fragrance materials during U.S. and European wastewater treatment. Environ Sci Technol. 2002 Jul 1;36(13):2839-47. PubMed PMID: 12144256.

[3] EN05. Research Institute for Fragrance Materials, Inc. (RIFM). 2002. ^{14}C-OTNE removal and/or biodegradation of a semi-volatile organic compound in an activated sludge simulation system.

- Conc. OTNE Influent$_{POTW}$ = 0.00032 mg/L

4. Finally, the concentration in the effluent of the POTW, which is released to receiving waters, is calculated by applying the measured removal rate of 90% from EPISUITE STP modeling and supporting studies:[4,5]
   - Conc. OTNE Effluent$_{POTW}$ = 0.00032 mg/L * 0.1 (fraction remaining after 90% removal)
   - **Conc. OTNE Effluent$_{POTW}$ = 0.000032 mg/L or 32 parts per trillion**

[4] EN22. Simonich SL, Federle TW, Eckhoff WS, Rottiers A, Webb S, Sabaliunas D, de Wolf W. Removal of fragrance materials during U.S. and European wastewater treatment. Environ Sci Technol. 2002 Jul 1;36(13):2839-47. PubMed PMID: 12144256.

[5] EN05. Research Institute for Fragrance Materials, Inc. (RIFM). 2002. ^{14}C-OTNE removal and/or biodegradation of a semi-volatile organic compound in an activated sludge simulation system.

Appendix VI. Information Relevant to Human Health and the Environment, Persistence and Bioaccumulation Potential.

1. Physical and chemical properties

Property	Description of key information	Reference
Physical state	Liquid at 20°C and 101.3 kPa https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/2	
Melting/freezing point	-20°C at 101.3 kPa https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/3	PC01
Boiling point	290.4°C at 101.3 kPa https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/4	PC02
Relative density	0.964 at 20°C https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/5	PC03
Granulometry	The substance is a liquid and is thus marketed in a non-solid or granular form. https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/6	
Vapour pressure	0.233Pa at 23°C https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/7	PC04
n-Octanol/water partition coefficient (log KOW value)	Log Kow (Log Pow): 5.65 at 30°C https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/8	PC05
Water solubility	2.68mg/L at 20°C https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/9	PC06
Surface tension	Surface tension is not expected, because of the absence of hydrophobic chains and hydrophilic heads and it is not a desired property of the substances. https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/11	
Flash point	134°C at 1013 hPa https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/12	PC07
Autoflammability/self-ignition temperature	260°C at 1013 hPa https://echa.europa.eu/registration-dossier/-	PC08

	/registered-dossier/15069/4/13	
Flammability	Non flammable https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/14	
Explosive properties	Non explosive https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/15	
Oxidizing properties	Non oxidizing https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/16	
Stability in organic solvents and identity of relevant degradation products	The substance is considered to be stable in organic solvents based on chemical structure and experience in use. https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/18	
Dissociation constant	The substance has no ionisable groups as can be concluded from its molecular structure and, therefore, its pKa is irrelevant in the chemical safety assessment. https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/22	
Viscosity	Viscosity: 32.61mPa s (dynamic) at 20°C https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/4/23	PC09

2. Human health

Endpoints	Study Summaries	Test Guideline	References
Acute oral toxicity	• LD50 (rat) > 5000 mg/kg • One dose group of 5000 mg/kg in 10 male and 10 female rats via oral gavage • No death during the 72-hr observation period https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/3/2	NA	HH01
Acute dermal toxicity	• LD50 (rat) > 5000 mg/kg • One dose group of 5000 mg/kg in 8 male and 8 female rats via dermal application (open to air for 24hr) • No death throughout the 14-day observation period https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/3/4	NA	HH02
Skin irritation	In vitro EPISKIN irritation • Self-classified as irritant • EPISKIN model with 15 minutes test item treatment and 42 hours incubation after rinsing off test item • Mean tissue viability 48.8 ± 9.2% https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/4/2/?documentUUID=8878e658-cb85-42d9-8c5f-25403648537e	OECD 439 GLP compliant	HH03
	Irritation in humans • No or negligible dermal irritation potential at test concentration of up to 75% in EtOH: DEP (1:3 or 3:1) • 24hr occlusive patch one application • Total 23 subjects completed the experiment • 25 mm Hill Top chamber patch, 0.3 ml each patch https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/4/2/?documentUUID=a0b1d6a4-1fd9-4d90-8a27-533c6317394c	NA	HH04

Skin sensitization	Local Lymph Node Assay in mouse (LLNA) • EC3 6.07%, 14.2%, 25.14%, • Doses of 2.5%, 10%, 25%, 50% and vehicle control (EtOH:DEP 1:3) • Each group 4 female mice (in 2005 study) and 5 female mice (in 2008 studies) treated on the dorsal surface of each ear once per day for 3 days • No overt toxicity or irritation seen https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/5/2/?documentUUID=1680fa85-78cd-4db3-9245-a67c11191693 https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/5/2/?documentUUID=36bb5bbc-b5eb-450e-a21c-53ac8f265bc9 https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/5/2/?documentUUID=e24ec02d-7ab0-4922-8d33-924822aa6102	OECD 429 OPPTS 870.2600 GLP compliant	HH05, HH06, HH07
	Human Repeated Insult Patch Test (HRIPT) • Not demonstrating sensitization at test concentration of 40% in EtOH:DEP (1:3) • Modified Draize patch test including induction (9 applications), a rest period (10-17 days) and a challenge (1 application) • Total 101 subjects completed the test • 25 mm Hill Top chamber patch, 0.3 ml each application https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/5/2/?documentUUID=2b815aaf-8d83-43ab-8f4a-e70d7d92cd0c	NA	HH08
Repeated-dose toxicity	28-day study in rats via oral gavage • NOAEL was considered at 150 mg/kg/day with liver finding (hepatocyte enlargement) at high dose (both sexes). Male rats specific kidney finding also observed at mid and high doses • Oral gavage with doses of 15, 150, 1000 mg/kg/day and control (corn oil) for 4 weeks	OECD 407 GLP compliant	HH09

	• A 2-wk recovery group included for control and high dose treatments • Each group 5 males and 5 females https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/6/2/?documentUUID=fbb0c7ce-375b-41d6-b022-726d03860610		
	13-week study in rats via oral gavage • NOAEL can be set at 120 mg/kg/day considering microscopic changes in spleen (erythropoiesis), associated with changes red blood cell system and weight of spleen at high dose • Oral gavage with doses of 30, 120, 500 mg/kg/day and control (corn oil) for 13 weeks • Each group 10 males and 10 females • Findings in male kidney (all doses, alpha-2u-globulin related) and liver (males all doses and females of mid and high doses, hepatocellular hypertrophy and vacuolation) were not considered as toxicological significant or adverse effects https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/6/2/?documentUUID=25ea3a80-1698-49f6-bfc3-6b6a59971860	OECD 408 GLP compliant	HH10
	13-week study in rats and mice via dermal • Dermal application with doses of 0, 6.25, 12.5, 25, 50, 100% and solvent control (EtOH) 5 days per week for 3 months, untreated control also included • Corresponding to 31.25 – 500 mg/kg in rats and 125 – 2000 mg/kg in mice • Each group 10 males and 10 females • Micronucleus assay in peripheral blood were also conducted at the end of study • Bacterial mutagenicity test was performed using the same lot of test material as in the 13-wk studies https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/6/4/?documentUUID=69af060f-e766-45f5-ba2c-ad2acaf7b070	NA	HH11

	https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/6/4/?documentUUID=ed6d0995-d724-4b33-883e-50adeab65690 https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/7/3/?documentUUID=97b1cbbe-244c-41ac-be3c-ec49e31fbd30 https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/7/3/?documentUUID=76dc550c-144a-4bdc-b558-fbf4e64e4495		
Developmental toxicity	Pre-natal developmental study in rats via oral gavage • NOAEL was considered at 240 mg/kg/day with significant decrease in body weight gain in dams and decrease (not statistically significant) of fetal body weight at high dose • Oral gavage with doses of 96, 240 and 480 mg/kg/day and control (water) during gestational days 7-17 • Each group 25 pregnant females https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/9/3/?documentUUID=af17f38a-b47e-4aad-8f18-d648df496575	ICH guideline GLP compliant	HH12
	Pre-natal developmental study in rabbits via oral gavage • NOAEL for maternal toxicity was considered at 200 mg/kg/day with increased relative liver weight and decreased food consumption and body weight change • NOAEL for developmental toxicity was considered at 500 mg/kg/day with absence of effects on implantation sites and fetal development • Oral gavage with doses of 75, 200 and 500 mg/kg/day and control (corn oil) during gestational days 6-28 • Each group 22 pregnant females *Before REACH dossier being updated with this study, the IUCLID summary is available upon request*	OECD 414 GLP compliant	HH13
Reproductive toxicity	Extended one generation reproductive toxicity study in Han Wistar rat by oral gavage administration	OECD 443 GLP compliant	HH21

	• Dose levels were 30, 100, and 300 mg/kg/day in the F0 generation • F1 generation was treated at the same dose levels as the F0 generation • F0 male and female animals were treated for approximately 120 days • F1 cohort A male and female animals were treated for approximately 70 days • F1 cohort B male and female animals were treated for approximately 77 days • NOAEL for systemic toxicity in the F0 and F1 cohort A adult animals was concluded to be the high dose of 300 mg/kg/day • NOAEL for reproductive performance of the F0 and F1 animals was concluded to be the high dose of 300 mg/kg/day for both males and females		
Genotoxicity/Mutagenicity	Bacterial mutation assay (AMES) • Negative • Test strains TA 1535, 1537, 1538, 98 and 100 as well WP2 uvrA • Test concentrations up to 5000 ug/plate https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/7/2/?documentUUID=d4912f5d-2de9-426c-bb6a-34a219ecae2a	OECD 471 GLP compliant	HH14
	In vitro mutation test in mouse lymphoma L5178Y cells • Negative • Three different test conditions: 3hr treatment with or without S9, and 24hr treatment without S9 • Concentration selected for mutation analysis spanned the toxicity range of 100-10% RTG https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/7/2/?documentUUID=021b5448-06c5-4674-8b46-a58de9ce4397	OECD 476 GLP compliant	HH15

	In vitro chromosome aberration in human lymphocytes • Negative • Test conditions were 3hr treatment with or without S9, followed by 18 or 32hr incubation • Doses chosen for metaphase analysis had acceptable toxicity (with a decrease in mitotic index of 50% of solvent control as the highest dose) https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/7/2/?documentUUID=56b151f8-ed42-42ea-9b7b-89d071927adb	OECD 473 GLP compliant	HH16
Other endpoints	Skin adsorption in human donated skin • Permeation 15.3% of the applied dose permeated into the receptor phase and 1.2% into the epidermis at 48hr, with an overall recovery of 53.3% due to volatility • Evaporative loss from PTFE over 48hr was 43% • Human skin obtained from cosmetic surgery was used to build Franz-type diffusion cells • [^{14}C] labelled test item https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/2/3/?documentUUID=963cb2b8-6463-4a8a-adaf-19eb172fe582	FDA/AAPS guidelines GLP compliant	HH17
	Placenta and milk transfer during and after pregnancy in rats • Oral gavage with doses of 2 and 20 mg/kg/day between gestation D14 and parturition D7 • Each group 18 pregnant rats • [^{14}C] labelled test item • Milk and blood samples were taken at 4, 8 and 24 hours on Days 3 and 7 after parturition for concentration measurement • Radioactivity concentration peaked at 4hr and declined at 24hr on both parturition D3 and D7 in plasma for both dose groups, with about 10x higher level in the high dose group than the low dose group	GLP compliant	HH18

	• Similar pattern in milk, with about 10-19x higher level in the high dose group than the low dose group • Test compound was not detected in the extracted milk samples at any sampling times for both dose groups indicating complete metabolism • Radioactivity barely detected in the fetus from rats with oral dose of 2 mg/kg/day for between gestation D14 and D19 and sacrificed at 4 and 24hr after the last dose https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/2/2/?documentUUID=7e1e3049-9d45-456c-8524-d2ba22fd2528		
	Deposition in male rats following oral or dermal exposure • Single dose via oral at 20 mg/kg or dermal at 55 or 550 mg/kg to covered or uncovered site in male Fisher rats • [^{14}C]beta-OTNE • Groups of 4 rats at each sacrificed time for each application • 48 hr following oral administration, 28% and 39% of the dose was recovered in urine and feces, respectively, in intact rats; about 73% of the dose was excreted in bile within 48h post-administration in bile duct cannulated model, with 12.8% and 2.8% in urine and feces, respectively • Adsorption was low (~14%) and dose-independent at 96 hr following dermal application to a covered site; adsorption increased (~33% at 55 mg/kg and ~72% at 550 mg/kg) when the dose site uncovered • Tissue distribution following both exposure routes were bladder, liver, kidney, adipose and pancreas https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/2/2/?documentUUID=44cec847-2bd0-414e-8304-5279501b31d8 https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15069/7/2/3/?documentUUID=10edbcf9-09c6-42a5-b93b-3f8dd24bfda6	NA	HH19

Biomonitoring	Residents of mothers in southwestern China, n=110 • Sampling year, 2009 • OTNE was detected in breast milk samples at reported levels less than 1.5 ng/g lipid	NA	HH20

3. Environmental Fate

3.1 Persistency

Multiple lines of evidence are available that indicate OTNE is not persistent in diverse environmental media when compared to EPA persistency criteria. While OECD 301 screening studies indicate OTNE is not "readily biodegradable," U.S. Food and Drug Administration (FDA) aerobic soil and sediment simulation studies, equivalent to the OECD 307, demonstrate significant biotransformation and mineralization with OTNE parent compound half-life values ranging from 4.2 to 6.0 days in agricultural and sludge-amended soil, respectively, to 9.5 days in river water sediment (EN03). In this study, 50-67.4% mineralization (CO_2 evolution) was measured at 12 weeks, depending on whether soil or sediment was tested, suggesting that the metabolites are not persistent in the environment. The metabolites were also determined to have greater polarity than the parent compound indicating lower toxicity based on the relationship of toxicity with polarity for chemicals that are neutral organics.

The high-rate of biotransformation of OTNE observed in soil and sediment has been reproduced in activated sludge and river-water die-away simulation studies. During a 28-day river water die-away test, degradation half-lives of <2 and 5 days were measured for OTNE (EN02). An activated sludge simulation study demonstrated 89% of OTNE is removed at steady-state solely due to the biotransformation of the parent compound (EN05). In all cases, OTNE was rapidly biotransformed into polar, water-soluble metabolites and in select cases significant mineralization was measured. In the activated sludge simulation study, HPLC was used to calculate Log K_{ow} of OTNE and its metabolites. OTNE, with a calculated average Log K_{ow} of 6.63-6.86, degraded into a major product in the waste water effluent that had a calculated average Log K_{ow} of 1.75-2.03.

The long-range transportation potential and atmospheric lifetime of OTNE, assessed in a non-guideline laboratory study (EN06), supported EPISuite modeling that demonstrated rapid atmospheric transformation. In this study, rate constants for transformation of OTNE were measured upon exposure to atmospheric relevant concentrations of free radicals to allow gas-phase reactions. In the presence of hydroxyl and nitrate radicals, OTNE had a half-life of 1.4 hours and 2 minutes, respectively. The kinetic data indicated that the atmospheric lifetime of OTNE is sufficiently short to prevent long-range transportation.

Field studies conducted in the U.S. that measured the fate of OTNE support the above laboratory-based studies. Removal rates in WWTPs were measured for OTNE based on influent and effluent concentrations and ranged from 89.7-96.8% removal for operations employing secondary treatment (see Appendix III). Significant removal was also observed from primary treatment providing indication that even low technology plants extensively remove OTNE. In addition to these field studies, an OTNE-sludge amended soil dissipation study under outdoor agricultural field conditions has been performed to simulate the scenario where OTNE is applied via biosolid application (EN24). The study provided evidence that OTNE is removed to levels below the limit of detection after 1 years' time and that the leaching of OTNE into deeper parts of the soil column is negligible.

Collectively, these studies demonstrate that OTNE and its metabolites are not persistent in the environment. OTNE is rapidly biotransformed to polar metabolites in all environmental compartments. The polar metabolites formed have lower log K_{ow}, where measured (measured Log K_{ow} <2), and are therefore anticipated to be less toxic and non-bioaccumulative. While the polar metabolites measured

were found to biodegrade at a slower rate than the parent compound, studies in sediment and soil both illustrate complete mineralization within timeframes that are indicative of non-persistent chemicals.

Method	Results	Reference
OECD Guideline 301 C (Ready Biodegradability: Modified MITI Test (I))	Not readily biodegradable % Degradation of test substance: 11% after 28d https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/5/3/2	EN01
Equivalent to OECD TG 314 Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Waste Water: Treated effluent in the mixing zone of surface water (*i.e.*, river water).	Half-life (DT50): 1 d in entire system at 20°C % Degradation of test substance: Ca.50% after 5h (Rad-TLC) (Primary degradation of parent (Rf 0.59 - 0.63)) 95% after 7d (Rad-TLC) (Primary degradation of parent (Rf 0.59 - 0.63)) Ca.100% after 14d (Rad-TLC) (Primary degradation of parent (Rf 0.59 - 0.63)) Transformation products: Yes, the transformation products were more polar than the parent substance https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/5/3/3/?documentUUID=f46a8471-2ad8-4134-b3b9-2be7cc8b2477	EN02
Equivalent to Environmental Assessment Technical Assistance Document 3.12, Aerobic biodegradation in soils and sediments. U.S. Food and Drug Administration, Washington DC, PB87-175345, 1987: Natural river sediment	Half-life (DT50): 9.5 d in sediment % Degradation of test substance: 90% after 3wk (test mat. analysis) (10% of parent material remaining in the microcosm, thus 90% primary degradation) >99% after 12wk (test mat. analysis) (0.53% of parent material remaining in the microcosm. Thus, primary degradation was almost complete.) 50% after 12wk (CO_2 evolution) Transformation products: Yes, the transformation products were more	EN03

	polar than the parent substance https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/5/3/3	
Equivalent to Environmental Assessment Technical Assistance Document 3.12, Aerobic biodegradation in soil. U.S. Food and Drug Administration, Washington DC, PB87-175345, 1987: Sludge-amended soil, and agricultural soil Soil type: Sludge amended agricultural soil (#1) Agricultural soil (#2)	Half-life (DT50): 4.2 d (#1) (using the amount of parent substance remaining at each time point) 6 d (#2) (using the amount of parent substance remaining at each time point) % Degradation of test substance: 77% after 3wk (test mat. analysis) (#1) 99.7% after 12wk (test mat. analysis) (#1) 61.7% after 12wk (CO2 evolution) (#1) 72% after 3wk (test mat. analysis) (#2) 98.9% after 6wk (test mat. analysis) (#2) 67.4% after 12wk (CO2 evolution) (#2) Transformation products: Yes, the transformation products were more polar than the parent substance https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/5/3/4	EN02
Dissipation under agricultural field conditions; outdoor die-away study in four sludge amended soils	Decreased steadily from 6-9 mg/kg dw soil to 1-3 mg/kg dw soil after 3 months After 1 year the substance was below limit of detection Low level of leaching occurred (< 1%) suggesting that OTNE is not significantly transported in soil columns	EN04
Activated sludge simulation study with radiolabeled OTNE	89% removal at steady state based on parent compound with remaining radioactivity lost due to mineralization, volatile loss and sorption OTNE, with a calculated average Log K_{ow} of 6.63-6.86, was degraded into the major product found in the waste water effluent, which had a calculated average Log K_{ow} of 1.75-2.03 using HPLC	EN05
No guideline available.	Half-life (DT50):	EN06

The reaction rate of OTNE with gas phase OH and NO3 radicals and O3 was measured using black lamps under normal atmospheric conditions. Rate constants were determined using relative disappearance rates of OTNE and a reference compound, whose OH radical, NO3 radical or O3 reaction rate is reliably known.	1.3 h (Reaction with OH radicals, estimated for 12-h daylight average OH radical concentration of 1.5 * 10^6 mol/cm3) 1 h (Reaction with OH radicals, estimated for 12-h daylight average OH radical concentration of 2 * 10^6 molecules/cm3) 1.4 min (Reaction with NO3 radicals, estimated for 12-h nighttime NO3 radical concentration of 5 * 10^8 mol/cm3) 5.5 d (Reaction with O3 radicals, estimated for 24-h average concentration of 7 * 10^11 mol/cm3)	

3.2 Environmental Distribution

Method/Guideline	**Results**	**References**
Adsorption/desorption under field conditions in sewage treatment plants	Log Koc: 4.12 https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/5/5/2	EN07

3.3 Bioaccumulation

The bioaccumulation potential of OTNE and its metabolites have been assessed in *Lepomis macrochirus* following the OECD 305 guideline and have been concluded to be non-bioaccumulative when compared to EPA criteria (EN08). In this study, the aqueous bioconcentration factor (BCF) of OTNE and its metabolites were determined via total radioactivity. OTNE was found to be rapidly metabolized by *Lepomis macrochirus* to polar, water-soluble products that were readily excreted. The rapid metabolism of the parent compound observed in this study parallels that to what has been observed in aforementioned fate and biodegradation studies. When accounting for growth dilution and lipid normalization, the modeled kinetic BCF and where possible the BCF at steady state based on total radiolabeled residues were well below the U.S. EPA's cutoff for bioaccumulation. The kinetic BCF agreed well with the BCF at steady state suggesting that there were no complications due to growth dilution. The bioaccumulation potential of OTNE as determined by total radiolabeled residues is considered conservative as it accounts for the bioaccumulation potential of the parent compound and its metabolites.

This study concludes that OTNE is non-bioaccumulative and rapidly metabolized into non-bioaccumulative readily excreted transformation products.

Method/Guideline	**Results**	**References**
Bioaccumulation in *Lepomis macrochirus* [fish] according to EPA OPPTS 850.1730 (Fish BioconcentrationTest);	BCF: BCF steady state, lipid corrected: 444 based on whole body wet weight (w/w) and total radioactivity (TRR) at steady state (dose:1.3 ug/l)	EN08

according to OECD Guideline 305 (Bioconcentration: Flow-through Fish Test) [before 2 Oct 2012]	BCF steady state, lipid corrected: 539 based on whole body w/w and TRR at steady state (dose:13 ug/l) Negligible impact from growth dilution Kinetic BCF in agreement with the steady state BCF Elimination: Yes; DT50 = 1.2d Transformation products: Metabolism by *Lepomis* was extensive. In fish fillet, OTNE was the major radioactive residue. In total, 6 byproducts, including OTNE, were detected. In fish viscera, OTNE (approximately 50% of TRR) as well as two major polar metabolites (comprising 30% to 35% TRR) were observed. In viscera, approximately 7-10 components were detected. Significant metabolites were found in exposure water indicating metabolites were readily excreted. https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/5/4/2	

4. Environmental Toxicity Data

4.1 Aquatic compartment

Test species	Method	Results	References
Algae (*Scenedesmus subspicatus*)	Comparable to OECD 201	72h-NOEC ≥ 2.6 mg/l 72h-EbC50> 2.6 mg/l 72h-ErC50> 2.6 mg/l https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/2/6	EN09
Daphnia magna	Comparable to OECD 202	48h-EC50= 1.38 mg/l <1.32 – 1.44> https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/2/4	EN10
Daphnia magna	OECD 211	21d-NOEC (repr.) = 0.028 mg/l 21d-EC50(repr.) = 0.285 mg/l <0.122 – 0.663> https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/2/5	EN11
Bluegill *(Lepomis*	Comparable to	96h-LC50= 1.3 mg/l <1.2 – 1.5>	EN12

macrochirus)	OECD 203	https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/2/2	
Zebra fish *(Danio rerio)*	OECD 210	30d-NOEChatch ≥ 0.54 mg/l 30d-NOECsurv. during yolk sac period ≥ 0.54 mg/l 30d-NOEC surv. larvae = 0.30 mg/l 30d-NOEC growth = 0.16 mg/l https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/2/3	EN13

4.2 Sediment compartment

Test species	**Guideline**	**Results**	**References**
Lumbriculus variegatus	Comparable to OECD 225	NOEC (28d): 17.1 mg/kg sediment dw test mat. (meas. (geom. mean)) based on: reproduction NOEC (28d): 33.3 mg/kg sediment dw test mat. (nominal) based on: total biomass NOEC (28d): >=100 mg/kg sediment dw test mat. (nominal) based on: mortality EC50 (28d): 96.6 mg/kg sediment dw test mat. (nominal) based on: reproduction https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/3/?documentUUID=49e2ba44-6124-4ed3-a122-a24aa5927931	EN14, EN15
Hyalella azteca	Comparable to OECD 218	NOEC (28d): 18.4 mg/kg sediment dw test mat. (meas. (geom. mean)) based on: mortality - and total biomass NOEC (28d): >=130 mg/kg sediment dw test mat. (nominal) based on: amphipod length EC50 (28d): 197.9 mg/kg sediment dw test mat. (nominal) based on: mortality https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/3/?documentUUID=3cc13e28-322f-49fb-910f-49d2181f1cae	EN15, EN16
Chironomus riparius	Comparable to OECD 218	NOEC (28d): 102 mg/kg sediment dw test mat. (meas. (initial)) based on: additional observations: complete emergence, ability to fly and survival after emergence NOEC (28d): 200 mg/kg sediment dw test mat. (nominal) based on: additional observations: complete emergence, ability to fly and survival after emergence	EN15, EN17

		NOEC (28d): 400 mg/kg sediment dw test mat. (nominal) based on: emergence rate - males and females pooled NOEC (28d): >=1000 mg/kg sediment dw test mat. (nominal) based on: development rate - males and females pooled EC50 (28d): 642 mg/kg sediment dw test mat. (nominal) based on: emergence rate - males and females pooled https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/3/?documentUUID=77d6dfe1-6440-402f-ae3c-fdd1580d4798	

4.3 Terrestrial compartment

Test species	Guideline	Result	References
Earthworms (*Eisenia fetida*)	OECD TG 222	NOEC28d: 100 mg/kg soil dw (mortality)NOEC28d: 31.6 mg/kg soil dw (body weight)NOEC56d: 31.6 mg/kg soil dw (reproduction) https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/4/2	EN18
Bacteria (Nitrogen Transformation test)	OECD 216	NOEC28d: 100 mg/kg soil dw (nitrate formation rate) NOEC28d: 100 mg/kg soil dw (nitrate content) https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/4/5	EN19
Terrestrial plants: *Allium cepa* *Avena sativa* *Cucumis sativus* *Solanum lycopersicum* *Glycine max (G. soja)* *Brassica napus*	OECD 208	*Brassica napus* EC10 (14d): 30 mg/kg soil dw (nominal) based on: growth *Glycine max (G. soja)* EC10 (14d): 24 mg/kg soil dw (nominal) based on: growth *Solanum lycopersicum* EC10 (14d): 15 mg/kg soil dw (nominal) based on: growth *Cucumis sativus* EC10 (14d): 50.3 mg/kg soil dw (nominal) based on: growth *Avena sativa* EC10 (14d): 19.4 mg/kg soil dw (nominal) based on: growth *Allium cepa* EC10 (21d): 24 mg/kg soil dw test mat. (nominal) based on: growth https://echa.europa.eu/registration-dossier/-/registered-dossier/15069/6/4/4	EN20

Appendix VII -- Storage of Chemical Substance near Significant Sources of Drinking Water, Including Storage Facility Location and Nearby Drinking Water Source(s)

Octahydro-tetramethyl-naphthalenyl-ethanone (OTNE) storage locations typically have spill prevention control and countermeasure plans in place and/or utilize other containment measures or practices to minimize the potential for any accidental releases involving OTNE.

The data regarding the environmental fate and its physicochemical properties, provided in Appendix VI, support that OTNE degrades rapidly in the environment and is not mobile in environmental field studies and simulation tests. As a result, the potential for OTNE contamination of drinking water is low. The submitting entities fully expect that EPA's risk evaluation review will support this conclusion. Although the likelihood of drinking water contamination is low, the submitting entities recognize its obligation to report on storage of OTNE near significant sources of drinking water without regard to the risk of contamination.

In accordance with 40 C.F.R. Section 702.37(b)(4)(iv) and the requirement to provide information regarding storage of neat OTNE near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s), each submitting entity has identified reasonably ascertainable locations where it stores neat OTNE, and to the extent practicable, nearby groundwater and surface water bodies from which community water systems[1] may source water. Using U.S. Environmental Protection Agency's (EPA) drinking water supply database[2], the submitting entities identified drinking water providers classified as community water systems that obtain water from sources within the watershed in which storage facilities are located. The annual water quality reports of the community drinking water providers were reviewed to identify surface and groundwater supply sources. Where a water system sourced drinking water from other drinking water systems, the annual water quality reports for those water systems were also reviewed.

The summary tables that follow include:

- Groundwater sources identified in annual water quality reports from which the applicable drinking water systems obtain drinking water;
- Surface water sources (identified in annual water quality reports) that are within one mile of a storage facility, from which the applicable drinking water systems obtain drinking water; and
- Surface water features within one mile of a storage facility located in watersheds where community water systems source drinking water from surface water, regardless of whether those features are sources of drinking water.

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1 Safe Drinking Water Act (SDWA) § 1401(15), 42 U.S.C. § 300f(15).

2 EPA, Drinking Water Mapping Application to Protect Source Waters, https://geopub.epa.gov/DWWidgetApp/.

Submitting Entity: International Flavors & Fragrances, Inc. (IFF)

Storage Address	Storage Type	Storage Location Description	Significant Community Drinking Water Systems	Surface Water and Groundwater Sources near Storage Location
IFF Chemical Holdings, Inc. 2051 N. Lane Avenue Jacksonville, FL 32254	Bulk process and holding tanks, ISO Containers, Poly totes.	Bulk process and holding tanks stored outdoors in enclosed vessels with secondary containment. ISO Containers stored temporarily outdoors within confines of the facility for product delivery. Poly totes stored temporarily indoors with secondary containment for product delivery	JEA Major Grid[3]	No surface water drinking water sources within the watershed in which this storage location is located Groundwater features: Floridian Aquifer
IFF 600 State Highway 36 Monmouth County Hazlet, NJ 07730	Bulk holding tanks, drums and totes	Bulk holding tanks stored indoors in enclosed vessels with secondary containment. Drums and totes stored temporarily	New Jersey American Water – Shorelands[4]	Surface water features within one mile; none are identified by water providers as sources of drinking water: East Creek, Flat Creek, Thornes Creek, Natco Lake Groundwater features: Upper, Middle, and Lower Potomac-Raritan-Magothy

[3] JEA, Jacksonville's Drinking Water System.

[4] New Jersey American Water, 2019 Annual Water Quality Report, Shorelands System.

Storage Address	Storage Type	Storage Location Description	Significant Community Drinking Water Systems	Surface Water and Groundwater Sources near Storage Location
		indoors with secondary containment.		(PRM) Aquifers
PSS Distribution Services Inc. 7 Nicholas Court Middlesex County Dayton, NJ 08810	Drums and totes.	Stored temporarily indoors within confines of the facility.	City of New Brunswick Water Utility[5]	Surface water features within one mile; none are identified by water providers as sources of drinking water: Lake Tarnofsky

[5] City of New Brunswick Water Utility, Water Quality Report 2020 for Calendar Year 2019.

Submitting Entity: Privi Organics USA Corp. (Privi)

Storage Address	Storage Type	Storage Location Description	Significant Community Drinking Water Systems	Surface Water and Groundwater Sources near Storage Location
Selective Transportation Corp. 20 Corporation Row Middlesex County Edison, NJ 08817	Drum and tote storage	Drums and totes are stored temporarily indoors, with provision of secondary containment, within confines of the storage facility	Middlesex Water Company[6] Middlesex Water Company purchases water from Raritan Water System[7] Raritan Water System purchases water from City of Newark Department of Water and Sewer Utilities[8]	Surface water feature within one miles of storage location: Raritan River Groundwater features: Brunswick, Stockton, Basalt, Passaic, and Glacial Drift Aquifers

6 Middlesex Water Company, 2019 Annual Water Quality Report.

7 New Jersey American Water, 2019 Annual Water Quality Report, Raritan System.

8 City of Newark Department of Water and Sewer Utilities, 2018 Annual Water Quality Report.

Submitting Entity: DRT America, Inc. (DRT)

Storage Address	Storage Type	Storage Location Description	Significant Community Drinking Water Systems	Surface Water and Groundwater Sources near Storage Location
Linden Bulk Transportation 4200 Tremley Point Road Union County Linden, NJ 07036	Tank, drum, and tote	Stored indoors with secondary containment	Suez Water New Jersey Rahway[9] Suez Water New Jersey Rahway purchases water from Middlesex Water Company[10] and New Jersey American Water – Raritan System[11] Raritan Water System purchases water from City of Newark Department of Water and Sewer Utilities[12]	Surface water features within one mile; none are identified by water providers as sources of drinking water: Rahway River (downstream of the North Branch of the Rahway River), Marshes Creek, Piles Creek, Pralls Creek Groundwater features: Brunswick, Stockton, Basalt, Passaic, and Glacial Drift aquifers

9 Suez Water Rahway Operations, 2019 Annual Drinking Water Quality Report.

10 Middlesex Water Company, 2019 Annual Water Quality Report.

11 New Jersey American Water, 2019 Annual Water Quality Report, Raritan System.

12 City of Newark Department of Water and Sewer Utilities, 2018 Annual Water Quality Report.

References

EN01. International Flavors & Fragrances Inc. (IFF). Test on biodegradability of ISO E SUPER by microorganisms.

EN02. Research Institute for Fragrance Materials, Inc. (RIFM). ^{14}C-OTNE (Iso E Super): Dieaway of a semi-volatile organic compound in river water.

EN03. International Flavors & Fragrances Inc. (IFF). FATE of OTAN (OTNE) in natural environments.

EN04. DiFrancesco AM, Chiu PC, Standley LJ, Allen HE, Salvito DT. Dissipation of fragrance materials in sludge-amended soils. Environ Sci Technol. 2004 Jan 1; 38(1):194-201. PubMed PMID: 14740736.

EN05. Research Institute for Fragrance Materials, Inc. (RIFM). ^{14}C-OTNE removal and/or biodegradation of a semi-volatile organic compound in an activated sludge simulation system.

EN06. Aschmann SM, Arey J, Atkinson R, Simonich SL. Atmospheric lifetimes and fates of selected fragrance materials and volatile model compounds. Environ Sci Technol. 2001 Sep 15; 35(18):3595-600. PubMed PMID: 11783633.

EN07. International Flavors & Fragrances Inc. (IFF). OTNE in sewage treatment plants and in sediment: measurements in southern Europe and in Berlin.

EN08. International Flavors & Fragrances Inc. (IFF). Bioconcentration test of ^{14}C-Iso E Super with bluegill, *Lepomis macrochirus*.

EN09. International Flavors & Fragrances Inc. (IFF). Acute toxicity of Iso-E-Super to *Scenedesmus subspicatus.*

EN10. International Flavors & Fragrances Inc. (IFF). Acute toxicity of Iso-E-Super to *Daphnia magna* under static-renewal conditions.

EN11. Research Institute for Fragrance Materials, Inc. (RIFM). *Daphnia magna*, 21-day chronic toxicity test with ^{14}C-OTNE (flow-through).

EN12. International Flavors & Fragrances Inc. (IFF). Acute toxicity of Iso-E-Super to Bluegill (*Lepomis macrochirus*) under static-renewal test conditions.

EN13. Research Institute for Fragrance Materials, Inc. (RIFM). Zebra Fish (*Danio rerio*), early-life stage toxicity test with ^{14}C-OTNE (flow-through).

EN14. International Flavors & Fragrances Inc. (IFF). A study on the toxicity to the aquatic oligochaete, *Lumbriculus variegatus*.

EN15. International Flavors & Fragrances Inc. (IFF). OTNE concentrations in sediment toxicity tests: Analytical results.

EN16. International Flavors & Fragrances Inc. (IFF). A study on the toxicity to the sediment dweller, *Hyalella Azteca*.

EN17. International Flavors & Fragrances Inc. (IFF). A study on the toxicity to the sediment dweller, *Chironomus riparius*.

EN18. International Flavors & Fragrances Inc. (IFF). Iso E Super: Effects on reproduction and growth of earthworms *Eisena fetida* in artificial soil.

EN19. International Flavors & Fragrances Inc. (IFF). Iso E Super: Effects on the activity of the soil microflora in the laboratory (nitrogen transformation).

EN20. International Flavors & Fragrances Inc. (IFF). Iso E Super: Effects on terrestrial (non-target) plants: Seedling emergence and seedling growth test.

EN21. McDonough K, Casteel K, Zoller A, Wehmeyer K, Hulzebos E, Rila JP, Salvito D, Federle T. Probabilistic determination of the ecological risk from OTNE in aquatic and terrestrial compartments based on US-wide monitoring data. Chemosphere. 2017 Jan; 167:255-261. doi:10.1016/j.chemosphere.2016.10.006. Epub 2016 Oct 8. PubMed PMID: 27728884.

EN22. Simonich SL, Federle TW, Eckhoff WS, Rottiers A, Webb S, Sabaliunas D, de Wolf W. Removal of fragrance materials during U.S. and European wastewater treatment. Environ Sci Technol. 2002 Jul 1;36(13):2839-47. PubMed PMID: 12144256.

EN23. Moldovan Z, Chira R, Alder AC. Environmental exposure of pharmaceuticals and musk fragrances in the Somes River before and after upgrading the municipal wastewater treatment plant Cluj-Napoca, Romania. Environ Sci Pollut Res Int. 2009 Aug;16 Suppl 1:S46-54. doi: 10.1007/s11356-008-0047-7. Epub 2008 Oct 30. PubMed PMID: 18972147.

EN24. Research Institute for Fragrance Materials, Inc. (RIFM). Review and evaluation of environmental emission scenarios for fragrance materials during compounding of perfume oils and formulation of consumer products.

EN25. Balk, Froukje, Blok, and Salvito. Personal Care Products-10 Environmental Risks of Musk Fragrance Ingredients. ACS symposium series. 2001, Jul 30;791:168-190. doi:10.1021/bk-2001-0791.ch010

HH01. International Flavors & Fragrances Inc. (IFF). Acute oral toxicity of Isocyclemone E in rats (single dose).

HH02. International Flavors & Fragrances Inc. (IFF). Acute dermal toxicity of Isocyclemone E in rats (single dose).

HH03. International Flavors & Fragrances Inc. (IFF). 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone: EPISKIN Skin irritation test $^{-42\ hours}$.

HH04. Research Institute for Fragrance Materials, Inc. (RIFM). Modified primary dermal irritation test with 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone (OTNE).

HH05. Research Institute for Fragrance Materials, Inc. (RIFM). Local Lymph Node Assay with 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone (OTNE).

HH06. Research Institute for Fragrance Materials, Inc. (RIFM). Local Lymph Node Assay with 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone (OTNE).

HH07. Research Institute for Fragrance Materials, Inc. (RIFM). Local Lymph Node Assay with 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone (OTNE).

HH08. Research Institute for Fragrance Materials, Inc. (RIFM). Repeated insult patch test (modified Draize procedure) with 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone.

HH09. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – four-week oral toxicity study in the rat with two-week recovery period.

HH10. International Flavors & Fragrances Inc. (IFF). Sub-chronic (13-week) oral gavage study with ISO E SUPER in rats.

HH11. National Toxicology Program (NTP). 2016. NTP technical report on the toxicity studies of octahydro-tetramethyl-naphthalenyl-ethanone (OTNE) administered dermally to F344/NTac rats and B6C3F1/N mice.

HH12. Research Institute for Fragrance Materials, Inc. (RIFM). Oral (gavage) developmental toxicity study of OTNE in rats.

HH13. International Flavors & Fragrances Inc. (IFF). An oral (gavage) prenatal development study with ISO E SUPER in New Zealand White rabbits.

HH14. International Flavors & Fragrances Inc. (IFF). ISO E SUPER - Bacterial mutation assay.

HH15. International Flavors & Fragrances Inc. (IFF). 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone: In vitro mutation test using mouse lymphoma L5178Y cells.

HH16. International Flavors & Fragrances Inc. (IFF). ISO E SUPER - Metaphase chromosome analysis of human lymphocytes cultured in vitro.

HH17. Research Institute for Fragrance Materials, Inc. (RIFM). In-vitro human skin penetration of eugenyl methyl ether, estragole, acetyl cedrene and OTNE.

HH18. Research Institute for Fragrance Materials, Inc. (RIFM). ^{14}C-OTNE: Investigation of the transfer across the placenta and into milk of rats during and after pregnancy following repeated oral administration.

HH19. Waidyanatha S, Ryan K. Disposition of fragrance ingredient [14C]1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)ethanone in male Fisher rats following oral administration and dermal application. Xenobiotica. 2014 Aug; 44(8):749-56. doi: 10.3109/00498254.2014.888489. Epub 2014 Feb 17. PubMed PMID: 24533629.

HH20. Yin J, Wang H, Zhang J, Zhou N, Gao F, Wu Y, Xiang J, Shao B. The occurrence of synthetic musks in human breast milk in Sichuan, China. Chemosphere. 2012 May; 87(9):1018-23. doi: 10.1016/j.chemosphere.2011.11.068. Epub 2011 Dec 21. PubMed PMID: 22196088.

HH21. International Flavors & Fragrances Inc. (IFF). OTNE: Extended one generation reproductive toxicity study in the Han Wistar rat by oral gavage administration.

PC01. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – Freezing Point Determination

PC02. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – Normal Boiling Point Estimate

PC03. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – Relative Density

PC04. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – Vapor Pressure

PC05. European Chemicals Agency (ECHA). Registration Dossier for EC 915-730-3. Partition coefficient n-octanol/water of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8.8-tetramethyl-2-naphthalenyl)ethanone (Iso E super).

PC06. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – Water Solubility

PC07. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – Flash Point

PC08. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – Auto-Ignition Temperature

PC09. International Flavors & Fragrances Inc. (IFF). ISO E SUPER – Viscosity Determination