HYDROGENATED OLIVE OIL

(CAS #226993-75-5)

GREENSCREEN® FOR SAFER CHEMICALS (GREENSCREEN®) ASSESSMENT

Prepared by:

ToxServices LLC

Assessment Date: December 26, 2024

Expiration Date: December 26, 2029

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GreenScreen® Executive Summary for Hydrogenated Olive Oil (CAS #226993-75-5)

Hydrogenated olive oil is used as a skin conditioning agent and viscosity controlling agent in cosmetics; no further uses were identified. Although limited data were identified for hydrogenated olive oil, there are adequate data for strong surrogates, including olive oil and other fatty acids oils high in oleic acid and similar fatty acids, to facilitate a comprehensive assessment. Hydrogenated olive oil is sold as solid, waxy flakes, and is not explosive or flammable at standard temperate and pressure. It has a very low estimated vapor pressure of 1E-20 mmHg at 25°C; therefore, it is not a volatile organic compound (VOC).

Hydrogenated olive oil was assigned a **GreenScreen Benchmark™ Score of 3_{DG}** ("Use but Still Opportunity for Improvement"). This score is based on the following hazard score combinations:

- A preliminary Benchmark score of 4, lowered to Benchmark 3_{DG} because of a data gap for endocrine activity (E).

Only one data gap was identified for endocrine activity (E). As outlined in GreenScreen® Guidance Section 11.6.2.1 and Annex 5 (Conduct a Data Gap Analysis), hydrogenated olive oil does not meet requirements for a GreenScreen Benchmark™ Score of 4 due to the hazard data gap. However, hydrogenated olive oil meets the data gap requirements for a Benchmark Score of 3. In a worst-case scenario, if hydrogenated olive oil were assigned a High score for the data gap endocrine activity (E), it would be categorized as a Benchmark 1 Chemical.

No previous GreenScreen® assessments were identified.

New Approach Methodologies (NAMs) used in this GreenScreen® include lack of experimental data and no relevant test method for the endpoint respiratory sensitization, and limitations associated with the use of *in vitro* test methods to assess genotoxicity. The quality, utility, and accuracy of NAM predictions are greatly influenced by two primary types of uncertainties:

- Type I: Uncertainties related to the input data used
- Type II: Uncertainties related to extrapolations made

Type I (input data) uncertainties in hydrogenated olive oil's NAMs dataset include lack of experimental data and no validated test methods to assess respiratory sensitization. Hydrogenated olive oil's Type II (extrapolation output) uncertainties include use of *in vitro* data to assess genotoxicity, which does not fully mimic *in vivo* metabolism.

GreenScreen® Hazard Summary for Hydrogenated Olive Oil

Group I Human					Group II and II* Human									Ecotox		Fate		Physical	
C	M	R	D	E	AT	ST		N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F
						s	r*	s	r*	*	*								
L	**L**	**L**	**L**	DG	**L**	**L**	**L**	*L*	**L**	*L*	*L*	**L**	**L**	**L**	*L*	**L**	*vL*	*L*	**L**

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect lower confidence in the hazard classification while hazard levels in **BOLD** font reflect higher confidence in the hazard classification. Group II Human Health endpoints differ from Group II* Human Health endpoints in that they have four hazard scores (i.e., vH, H, M, and L) instead of three (i.e., H, M, and L), and are based on single exposures instead of repeated exposures. Group II* Human Health endpoints are indicated by an * after the name of the hazard endpoint or after "repeat" for repeated exposure sub-endpoints. Please see Appendix A for a glossary of hazard acronyms.

GreenScreen® Chemical Assessment for Hydrogenated Olive Oil (CAS #226993-75-5)

Method Version: GreenScreen® Version 1.4
Assessment Type[1]: Certified
Assessor Type: Licensed GreenScreen® Profiler

GreenScreen® Assessment (v.1.4) Prepared By:
Name: Nancy Linde, M.S.
Title: Senior Toxicologist
Organization: ToxServices LLC
Date: December 4, 2024

Quality Control Performed By:
Name: Jennifer Rutkiewicz, Ph.D.
Title: Senior Toxicologist
Organization: ToxServices LLC
Date: December 26, 2024

Expiration Date: December 26, 2029[2]

Chemical Name: Hydrogenated Olive Oil

CAS Number: 226993-75-5

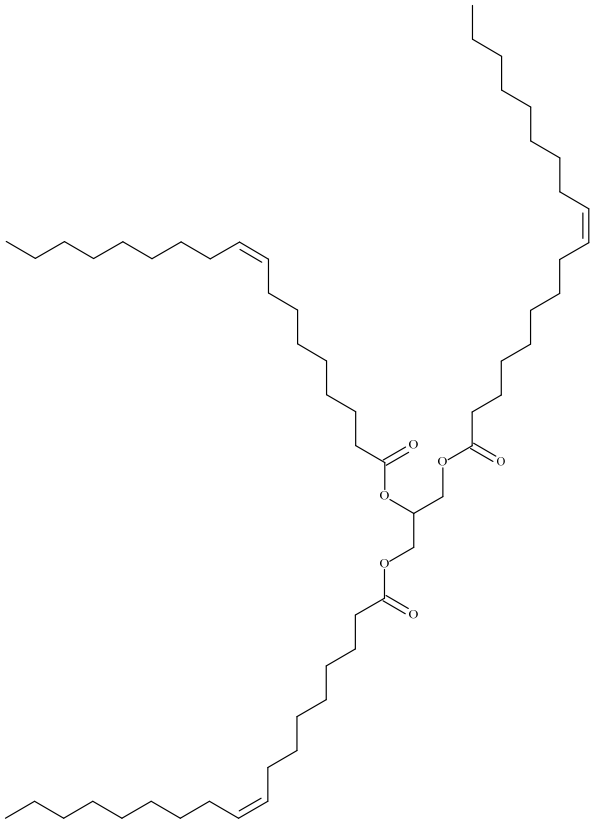
Chemical Structure(s): Not identified

Also called: Olive oil, hydrogenated (PubChem 2024).

Suitable surrogates or moieties of chemicals used in this assessment (CAS #'s):

Hydrogenated olive oil has very limited toxicological data; therefore, data for olive oil (CAS #8001-25-0) are used as surrogate data. The only difference between these chemicals is that the hydrogenated olive oil has fewer unsaturated fatty acids due to the hydrogenation process. Hydrogenation can affect viscosity, but is not expected to significantly affect toxicity. As olive oil is a UVCB, neither compound has a discrete structure. Olive oil consists primarily of the glycerides of linoleic, oleic, and palmitic acids (PubChem 2024). The Cosmetic Ingredient Review (CIR) Expert Panel reports average fatty acid content at 53-86% oleic acid (C18:1), 3.5—20% linoelic acid (C18:2), and 7.5-20% palmitic acid (C16) (CIR 2017). PubChem (2024) presents the structure for the triglyceride of oleic acid (glyceryl trioleate, CAS #122-32-7) (SMILES: CCCCCCCC/C=C\CCCCCCCC(=O)OCC(OC(=O)CCCCCCC/C=C\CCCCCCCC)COC(=O)CCCCCCC/C=C\CCCCCCCC).

[1] GreenScreen® reports are either "UNACCREDITED" (by unaccredited person), "AUTHORIZED" (by Authorized GreenScreen® Practitioner), or "CERTIFIED" (by Licensed GreenScreen® Profiler or equivalent).
[2] Assessments expire five years from the date of completion starting from January 1, 2019. An assessment expires three years from the date of completion if completed before January 1, 2019 (CPA 2018a).



Glyceryl trioleate (CAS #122-32-7) (PubChem 2024)

When no data were available for hydrogenated olive oil or the surrogate olive oil, ToxServices considered data on other plant derived oils, such as coconut oil (CAS #8001-31-8), hydrogenated coconut oil (CAS #84836-98-6), linseed oil (CAS #8001-26-1), palm oil (CAS #8002-75-3), palm kernel oil (CAS #8023-79-8), and hydrogenated soybean oil (CAS #8016-70-4). These chemicals were also used as read-across substances by the CIR Expert Panel in its safety assessment of 244 plant-derived fatty acid oils (CIR 2017). These surrogates are data rich, include oleic acid and other long chain fatty acid as part of their fatty acid content, and are considered strong surrogates. The REACH dossier for fatty acids, palm-oil, hydrogenated (CAS #84238-17-5) also includes read across data for pine nut oil (CAS #67701-30-8) (ECHA CHEM, CAS #84238-17-5, 2024b). Pine nut oil is also high in oleic and lineoleic acids at 24 and 48%, respectively (Takala et al. 2023); therefore, it is also a strong surrogate. Finally, castor oil (CAS #8001-79-4) was also used as a surrogate. Castor oil's fatty acid composition comprises up to 90% ricinoleic acid (CIR 2007), another C18 fatty acid; however, because ricinoleic acid is an unsaturated hydroxy acid, it is considered a weaker surrogate and is used as a supporting surrogate.

Identify Applications/Functional Uses:
1. Skin conditioning and viscosity controlling agent in cosmetics (CosIng 2024).

Known Impurities[3]:
Plant-derived oils in general may have impurities including heavy metals and pesticide residues that may be present in the raw material; additionally, the CIR Expert Panel noted that glycidol and glycidol

[3] Impurities of the chemical will be assessed at the product level instead of in this GreenScreen®.

fatty acid esters (considered possible carcinogens) may be present in plant-derived oils (CIR 2017). Information on residual impurities, if any, in hydrogenated olive oil, was not identified. This screen is performed on the theoretical pure substance.

GreenScreen® Summary Rating for Hydrogenated Olive Oil[4,5 6,7]**:** Hydrogenated olive oil was assigned a **GreenScreen Benchmark™ Score of 3_{DG}** ("Use but Still Opportunity for Improvement" due to Data Gaps) (CPA 2018b). This score is based on the following hazard score combinations:

- A preliminary Benchmark score of 4, lowered to Benchmark 3_{DG} because of a data gap for endocrine activity (E).

Only one data gap was identified for endocrine activity (E). As outlined in GreenScreen® Guidance Section 11.6.2.1 and Annex 5 (Conduct a Data Gap Analysis) (CPA 2018b), hydrogenated olive oil does not meet requirements for a GreenScreen Benchmark™ Score of 4 due to the hazard data gap. However, hydrogenated olive oil meets the data gap requirements for a Benchmark Score of 3. In a worst-case scenario, if hydrogenated olive oil were assigned a High score for the data gap endocrine activity (E), it would be categorized as a Benchmark 1 Chemical.

Figure 1: GreenScreen® Hazard Summary for Hydrogenated Olive Oil

Group I Human					Group II and II* Human									Ecotox		Fate		Physical	
C	M	R	D	E	AT	ST		N		SnS	SnR	IrS	IrE	AA	CA	P	B	Rx	F
						s	r*	s	r*	*	*								
L	**L**	**L**	**L**	DG	**L**	**L**	**L**	*L*	**L**	*L*	*L*	**L**	**L**	**L**	*L*	**L**	*vL*	*L*	**L**

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect lower confidence in the hazard classification while hazard levels in **BOLD** font reflect higher confidence in the hazard classification. Group II Human Health endpoints differ from Group II* Human Health endpoints in that they have four hazard scores (i.e., vH, H, M, and L) instead of three (i.e., H, M, and L), and are based on single exposures instead of repeated exposures. Group II* Human Health endpoints are indicated by an * after the name of the hazard endpoint or after "repeat" for repeated exposure sub-endpoints. Please see Appendix A for a glossary of hazard acronyms.

Environmental Transformation Products

Per GreenScreen® guidance (CPA 2018b), chemicals that degrade rapidly and completely (i.e., meet criteria for a Very Low for persistence) are not likely to form persistent biodegradation intermediates because the degradation intermediates will not persist long enough to be encountered after use or release of the parent chemical (i.e., relevant). As hydrogenated olive oil is readily biodegradable, it is not expected to have relevant transformation products.

[4] For inorganic chemicals with low human and ecotoxicity across all hazard endpoints and low bioaccumulation potential, persistence alone will not be deemed problematic. Inorganic chemicals that are only persistent will be evaluated under the criteria for Benchmark 4.
[5] See Appendix A for a glossary of hazard endpoint acronyms.
[6] For inorganic chemicals only, see GreenScreen® Guidance v1.4 Section 12 (Inorganic Chemical Assessment Procedure).
[7] For Systemic Toxicity and Neurotoxicity, repeated exposure data are preferred. Lack of single exposure data is not a Data Gap when repeated exposure data are available. In that case, lack of single exposure data may be represented as NA instead of DG. See GreenScreen® Guidance v1.4 Annex 2.

Table 1: Environmental Transformation Product Summary						
Life Cycle Stage	**Transformation Pathway**	**Environmental Transformation Product**	**CAS #**	**Feasible (Yes or No)**	**Relevant (Yes or No)**	**GreenScreen® List Translator Score or GreenScreen® Benchmark™ Score[8,9]**
N/A	N/A	N/A	N/A	N/A	N/A	N/A

N/A – Not applicable.

Introduction

Hydrogenated olive oil is used as a skin conditioning agent and viscosity controlling agent in cosmetics; it has historical use in personal care products with reported use levels up to 12% in leave-on products, and up to 0.1% in rinse-off products (CIR 2017). It is produced by hydrogenation of olive oil and is sold as solid waxy flakes (Hallstar Italia srl 2015).

ToxServices assessed hydrogenated olive oil against GreenScreen® Version 1.4 (CPA 2018b) following procedures outlined in ToxServices' SOPs (GreenScreen® Hazard Assessment) (ToxServices 2021).

U.S. EPA Safer Choice Program's Safer Chemical Ingredients List

The SCIL is a list of chemicals that meet the Safer Choice standard (U.S. EPA 2024a). It can be accessed at: http://www2.epa.gov/saferchoice/safer-ingredients. Chemicals on the SCIL have been assessed for compliance with the Safer Choice Standard and Criteria for Safer Chemical Ingredients (U.S. EPA 2024b). Hydrogenated olive oil is not currently on the SCIL.

GreenScreen® List Translator Screening Results

The GreenScreen® List Translator identifies specific authoritative or screening lists that should be searched to identify GreenScreen Benchmark™ 1 chemicals (CPA 2018b). Pharos (Pharos 2024) is an online list-searching tool that is used to screen chemicals against all of the lists in the List Translator electronically. ToxServices also checks the U.S. Department of Transportation (U.S. DOT) lists (U.S. DOT 2008a,b),[10] which are not considered GreenScreen® Specified Lists but are additional information sources, in conjunction with the Pharos query. The output indicates benchmark or possible benchmark scores for each human health and environmental endpoint. The output for hydrogenated olive oil can be found in Appendix C.

- Hydrogenated olive oil does not have a previous GreenScreen hazard score according to Pharos, and therefore a full GreenScreen® is required.
- Hydrogenated olive oil is not listed on the U.S. DOT list.

Hazard Statement and Occupational Control

No Globally Harmonized System of Classification and Labelling of Chemicals (GHS) hazard statements were identified for hydrogenated olive oil, as indicated in Table 2. General personal protective

[8] The GreenScreen® List Translator identifies specific authoritative or screening lists that should be searched to screen for GreenScreen Benchmark™ 1 chemicals (CPA 2018b). Pharos (Pharos 2024) is an online list-searching tool that is used to screen chemicals against the lists in the List Translator electronically.
[9] A GreenScreen® assessment of a transformation product depends on the Benchmark score of the parent chemical (see GreenScreen® Guidance).
[10] DOT lists are not required lists for GreenScreen® List Translator v1.4. They are reference lists only.

equipment (PPE) recommendations are presented in Table 3, below. No occupational exposure limits (OELs) were identified.

Table 2: GHS H Statements for Hydrogenated Olive Oil (CAS #226993-75-5) (ECHA 2024a)	
H Statement	**H Statement Details**
Not applicable	Not applicable
No harmonized GHS H statements are reported by the European Chemicals Agency (ECHA). According to the notifications provided by companies to ECHA in REACH registrations, no hazards have been classified.	

Table 3: Occupational Exposure Limits and Recommended Personal Protective Equipment for Hydrogenated Olive Oil (CAS #226993-75-5)			
Personal Protective Equipment (PPE)	**Reference**	**Occupational Exposure Limits (OEL)**	**Reference**
Not applicable		Not applicable	
No chemical-specific recommendations for PPE, and no OELs were identified. Precautions applicable to all chemicals may still apply (i.e., avoid contact with skin and eyes).			

Physicochemical Properties of Hydrogenated Olive Oil

Table 4: Physical and Chemical Properties of Hydrogenated Olive Oil (CAS #226993-75-5)		
Property	**Value**	**Reference**
Molecular formula	UVCB	
SMILES Notation	Variable (UVCB); Representative structure: CCCCCCCC/C=C\CCCCCCCC(=O)OCC(OC(=O)CCCCCCC/C=C\CCCCCCCC)COC(=O)CCCCCCC/C=C\CCCCCCCC	PubChem 2024
Molecular weight	Variable (UVCB)	
Physical state	Solid (waxy flakes)	Hallstar Italia srl 2015
Appearance	White to Ivory	Hallstar Italia srl 2015
Melting point	60-70°C	Hallstar Italia srl 2015
Boiling point	829.24 (Estimated based on representative SMILES)	U.S. EPA 2017, Appendix D
Vapor pressure	1E-20 mmHg at 25°C (estimated based on representative SMILES)	U.S. EPA 2017, Appendix D
Water solubility	Dispersible	Hallstar Italia srl 2015
Dissociation constant	Not applicable	
Density/specific gravity	Not identified	
Partition coefficient	Log K_{OW} = 18.75 (estimated based on representative SMILES)	U.S. EPA 2017, Appendix D

Toxicokinetics

No chemical specific toxicokinetic data were identified. However, as hydrogenated olive oil is expected to be very similar to olive oil, a common food, it is expected to be readily absorbed following ingestion, and as it is high in fatty acids, it is reasonable to expect it will be metabolized primarily in the liver, and be utilized as energy, stored as fat, or excreted in the feces.

Hazard Classification Summary

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M, or L): L

Hydrogenated olive oil was assigned a score of Low for carcinogenicity based on surrogate data. The surrogates coconut oil and palm oil were not tumorigenic in oral non-standard carcinogenicity studies. GreenScreen® criteria classify chemicals as a Low hazard for carcinogenicity when adequate and negative data are available, and they are not GHS classified (CPA 2018b). The confidence in the score is high as it is based on data of high quality for strong surrogates.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- CIR 2000, ECHA CHEM, CAS #84238-17-5, 2024b
  - *Surrogate: Coconut oil (CAS #8001-31-8):* In a long-term carcinogenicity study, 39-40 male and female Wistar rats per group were provided feed containing coconut oil at a dose equivalent to 54% of calories during their entire life span (104 weeks). The animals were evaluated for clinical signs, body weight, food consumption, gross pathology and histopathology. No statistically significant increase in the incidence of tumors was observed in treated rats. The study authors concluded that under the test conditions, coconut oil has low carcinogenic potential (Klimisch score 2, reliable with restrictions) (Unpublished 1972, 001 WOE).
  - *Surrogate: Palm oil (CAS #8002-75-3)*: In another study that was conducted to determine the effects of dietary palm oil on mammary tumorigenesis, female Sprague-Dawley rats (n=20) were given a single dose of 5 mg of DMBA and after three days were fed with semisynthetic diets containing 20% crude palm oil, for 5 months. No significant increase in tumor incidences was seen and palm oil did not have a non-promoting effect on chemically induced mammary carcinogenesis in female rats (Klimisch score 2, reliable with restrictions) (Unpublished 1989, 002 WOE)
  - *Surrogate: Palm oil (CAS #8002-75-3)*: In a study that was conducted to determine the effects of dietary fat (palm oil, corn oil) on mammary tumorigenesis, feed containing 20% palm oil had no effects on 12-dimethylbenz(a)anthracene (DMBA)-induced mammary tumorigenesis when fed to weanling 21-day old female Sprague-Dawley rats for 6 months following the initiation of carcinogenesis at 52 days of age (Klimisch score 2, reliable with restrictions) (Unpublished 1986, 003 WOE).

Mutagenicity/Genotoxicity (M) Score (H, M, or L): L

Hydrogenated olive oil was assigned a score of Low for mutagenicity/genotoxicity based on negative results for mutagenicity and clastogenicity in *in vitro* and *in vivo* assays performed with surrogates. While surrogate palm oil exhibited weakly positive results in Ames assays, study authors attributed it to lipid peroxidation, a process in which oxidants attacks carbon-carbon double bonds in unsaturated fatty acids. This process is not relevant to hydrogenated olive oil, as the hydrogenation process eliminates unsaturation. GreenScreen® criteria classify chemicals as a Low hazard for mutagenicity/genotoxicity when adequate data for genotoxicity and clastogenicity are available and negative and they are not GHS classified (CPA 2018b). The confidence in the score is high as it is based on measured data of high quality for strong surrogates.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.

  - *Screening:* Not present on any screening lists for this endpoint.
- ECHA CHEM, CAS #84238-17-5, 2024b (Note: Only studies reported in the REACH dossier with a reliability rating of 1 (reliable without restrictions) or 2 (reliable with restrictions) were included in the assessment)

  In vitro:
  - *Surrogate: Coconut oil (CAS #8001-31-8)*: Coconut oil was negative in an Ames assay using *Salmonella typhimurium* tester strains at concentrations up to 5,000 µg/plate (No further details were provided) (Klimisch score 2, reliable with restrictions) (Unpublished 1970, 001 WOE).
  - *Surrogate: Castor oil (CAS #8001-79-4): In vitro*: Castor oil was negative in an Ames assay conducted in a similar manner to OECD Guideline 471 in *S. typhimurium* tester strains TA 1535, TA 97, TA 98, and TA 100 in the presence and absence of metabolic activation. Castor oil was tested at concentrations up to 10,000 µg/plate in dimethyl sulfoxide (DMSO). No increase in the mutation frequency was observed in the presence or absence of metabolic activation. Vehicle and positive controls were reported as valid (Klimisch score 2, reliable with restrictions) (Unpublished 1992, 003 WOE).
  - *Surrogate: Castor oil (CAS #8001-79-4)*: *In vitro*: Castor oil was negative in a chromosome aberration study in Chinese hamster ovary (CHO) cells conducted in a similar manner to OECD Guideline 473. Cells were treated with 0, 1,600, 3,000, and 5,000 µg/mL castor oil in the presence and absence of metabolic activation. The test substance did not produce chromosomal aberration in CHO cells and was not cytotoxic under the experimental conditions. Vehicle and positive controls were reported as valid (Klimisch score 2, reliable with restrictions) (Unpublished 1992, 004 WOE).
  - *Surrogate: Castor oil (CAS #8001-79-4): In vitro*: Castor oil was negative in a sister chromatid exchange (SCE) assay in mammalian cells conducted in a similar manner to OECD Guideline 479. CHO cells were treated with 160, 500, 1,600, and 5,000 µg/mL castor oil in DMSO in the presence and absence of metabolic activation. The test substance did not produce significant SCEs in the treated cells. Vehicle and positive controls were reported as valid (Klimisch score 2, reliable with restrictions) (Unpublished 1992, 005 WOE).

  In vivo:
  - *Surrogate: Castor oil (CAS #8001-79-4):* Castor oil was tested in a GLP-compliant *in vivo* micronucleus test conducted in a similar manner to OECD Guideline 474. B6C3F1 mice (10/sex/dose) were fed the test material in feed at concentration of 0, 0.6, 1.3, 2.5, 5.0, and 10.0% for 90 days. There were no increases in the frequencies of micronucleated normochromatic erythrocytes from the bone marrow smears. No significant changes in the percentages of polychromatic erythrocytes were reported (Klimisch score 2, reliable with restrictions) (Unpublished 1992, 002 WOE).
- CIR 2000
  - *Surrogate: Palm oil (CAS #8002-75-3)*: Both refined and unrefined palm oil were weakly mutagenic in an Ames assay using a modified liquid incubation method in *S. typhimurium* strain TA1537 (metabolic activation not specified), but not in strains TA1538, TA7, TA100, and TA102. No evidence of mutagenicity was seen in any strain using standard plate incorporation or 20-minute plate pre-incubation protocols. The individual triacylglycerol and fatty acid fractions were not mutagenic, but the lipid peroxide fractions were weakly mutagenic; catalase eliminated mutagenicity, indicating the effect was mediated by hydrogen peroxide.

- *Surrogate: Palm oil (CAS #8002-75-3)*: In a second Ames assay in *S. typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538, weak mutagenicity was seen in all strains at a dose of 2 µL/plate but not at 1 µL/plate (metabolic activation not specified).
- *Surrogate: Palm oil (CAS #8002-75-3)*: No increase in chromosomal aberrations (gaps, breaks, fragments, and aberrations) in bone marrow was seen in female Balb/C mice that were administered 4.5 g/kg palm oil by gavage for 5 consecutive days and sacrificed 24 hours after the final dose.

Reproductive Toxicity (R) Score (H, M, or L): L

Hydrogenated olive oil was assigned a score of Low for reproductive toxicity based on lack of reproductive effects in oral reproductive toxicity studies conducted with surrogates. GreenScreen® criteria classify chemicals as a Low hazard for reproductive toxicity when adequate data are available and negative and they are not GHS classified (CPA 2018b). The confidence in the score is high as it is based on measured data of high quality for strong surrogates.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- ECHA CHEM, CAS #84238-17-5, 2024b, CIR 2000
  - *Surrogate: Palm kernel oil (CAS #8023-79-8):* No statistically significant effects on reproductive or developmental parameters were reported in a 2-generation oral toxicity study (guideline and GLP-compliance not specified). Mongolian gerbils were provided feed containing 8.75% palm kernel oil (5/sex) for generation 1, and all pups were put on the same feed. Evaluations included frequency of litters, number of pups, mean litter size, mean weight at 6 months of age, and postnatal mortality, and there were no treatment-related effects (no further details provided) (Klimisch score 2, reliable with restrictions) (Unpublished 1988, 001 WOE).
  - *Surrogate: Palm oil (CAS #8002-75-3):* In a combined repeated dose and reproductive screening study (non-guideline, and non-GLP), Sprague-Dawley rats (10 males, 20 females) were provided feed containing 15% heated or unheated palm oil (equivalent to 7,000 -17,000 mg/kg/day as calculated by ECHA dossier authors) for 10 weeks prior to mating, and dams and offspring were maintained on the same diet after weaning. Offspring were examined at 5 weeks of age. The animals were evaluated for clinical signs of toxicity, body weight, food consumption, hematology, clinical chemistry, gross pathology, and histopathology. Reproductive parameters (%implantation, %surviving young, % embryo loss) were also evaluated. No effects on reproductive parameters, implantation, litter size, offspring viability, or perinatal and postnatal survival were reported. Offspring of rats administered heated palm oil had increased relative liver (males and females) and kidney (females) weights compared to those administered untreated palm oil, which authors attributed to metabolic adaptation in the liver and did not consider to be toxicologically significant. Authors concluded that palm oil did not have adverse effects on fertility (Klimisch score 2, reliable with restrictions) (Unpublished 1977, 002 WOE).
  - *Surrogate: Palm oil (CAS #8002-75-3):* No statistically significant effects on reproductive or developmental parameters were seen in a 3-generation oral toxicity study performed according to the guidelines of the FDA/WHO/DGHS safety evaluation protocol (FDA, 1970). Wistar rats (12/sex) were provided feed containing 10% (9,200 mg/kg/day for males and 10,300 mg/kg/day for females) palm oil beginning 100-120 days prior to the mating of the F_0 rats. Reproductive parameters included percentage conception, birth, weight, litter size, weanling weight, sex ratio at birth and weaning, preweaning mortality and number of

days from introduction to mating (Klimisch score 2, reliable with restrictions) (Unpublished 1993, 003 WOE).

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M, or L): L

Hydrogenated olive oil was assigned a score of Low for developmental toxicity based on lack of developmental effects in reproduction/developmental toxicity oral studies conducted with surrogates. GreenScreen® criteria classify chemicals as a Low hazard for reproductive toxicity when adequate data are available and negative and they are not GHS classified (CPA 2018b). The confidence in the score is high as it is based on measured data of high quality for strong surrogates.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- ECHA CHEM, CAS #84238-17-5, 2024b, CIR 2000
  - *Surrogate: Palm kernel oil (CAS #8023-79-8):* No statistically significant effects on reproductive or developmental parameters were reported in the previously described 2-generation oral toxicity study in Mongolian gerbils provided feed containing 8.75% palm kernel oil. Offspring were evaluated for frequency of litters, number of pups, mean litter size, mean weight at 6 months of age and postnatal mortality levels (no further details provided) (Klimisch score 2, reliable with restrictions) (Unpublished 1988, 001 WOE (reproductive toxicity section)).
  - *Surrogate: Palm oil (CAS #8002-75-3):* No statistically significant effects on reproductive or developmental parameters were reported in the previously described 3-generation oral toxicity study in Wistar rats (12/sex) provided feed containing 10% (9,200 mg/kg/day for males and 10,300 mg/kg/day for females) palm oil beginning 100-120 days prior to the mating of the F_0 rats. Offspring were evaluated for survival, mean litter size, sex ratio, body weight, and external and internal abnormalities (Klimisch score 2, reliable with restrictions) (Unpublished 1993, 003 WOE (reproductive toxicity section)).
- CIR 2000
  - *Surrogate: Palm oil (CAS #8002-75-3):* Palm oil showed some evidence of developmental toxicity in a study with pregnant albino rats (strain not specified) administered 1, 2, or 3 mL palm oil (approximately 5,200, 10,400, or 15,600 mg/kg/day[11]) by gavage on gestation days 5-15. Fetal mortality and the incidence of malformations increased with dose, and stunted growth was reported in fetuses that survived until gestation day 20. Exencephaly, ocular defects, and cleft palate were seen at the high dose of 15,600 mg/kg/day. Authors noted that effects were similar to those caused by hypervitaminosis A and may have resulted from high carotene content of palm oil. The CIR Expert Panel noted that effects may also be attributed to the presence of one or more contaminants, such as benzo(a)pyrene, PCBs, or organochlorine pesticides, in palm oil.
- Based on weight of evidence a score of Low was assigned. Although some evidence of developmental toxicity was reported in a study with pregnant albino rats (strain not specified) administered the surrogate palm oil on gestation days 5-15, the effects were attributed to the presence of one or more contaminants, or the high vitamin A content of the palm oil. In addition, these effects occurred at high dose levels (≥5,200 mg/kg/day) that exceed current maximum doses recommended by OECD guidelines (i.e., 1,000 mg/kg/day). Other available studies on plant-derived oils indicated low potential for developmental toxicity for these ingredients.

[11] 1 mL = approximately 900 mg (ECB 2000) / 0.173 kg = 10,200 mg/kg (average female rat body weight, subchronic study http://www.tera.org/Tools/ratmousevalues.pdf)

Endocrine Activity (E) Score (H, M, or L): DG
Hydrogenated olive oil was assigned a score of Data Gap for endocrine activity based on lack of data.
Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- No data were identified.

Group II and II* Human Health Effects (Group II and II* Human)
Note: Group II and Group II* endpoints are distinguished in the v 1.4 Benchmark system (the asterisk indicates repeated exposure). For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints. See GreenScreen® Guidance v1.4, Annex 2 for more details.

Acute Mammalian Toxicity (AT) (Group II) Score (vH, H, M, or L): L
Hydrogenated olive oil was assigned a score of Low for acute toxicity based on a measured oral LD_{50} values greater than 2,000 mg/kg in rats exposed to the surrogate palm oil. GreenScreen® criteria classify chemicals as a Low hazard for acute toxicity when oral LD_{50} values are greater than 2,000 mg/kg (CPA 2018b). The confidence in the score is high as it is based on measured data of high quality for strong surrogates. No reliable acute dermal or inhalation data were found.
- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- ECHA CHEM, CAS #84238-17-5, 2024b, CIR 2000
  - *Oral:* *Surrogate: Coconut oil (CAS #8001-31-8):* LD_{50} > 5,000 mg/kg in rats (strain unspecified) (Klimisch 2, reliable with restrictions) (Unpublished 1970, 001 WOE).
  - *Oral:* *Surrogate: Coconut oil (CAS #8001-31-8):* LD_{50} > 23,500 mg/kg in rats (strain unspecified) (Klimisch 2, reliable with restrictions) (Unpublished 2000, 002 WOE).
  - *Oral:* *Surrogate: Castor oil (CAS #8001-79-4):* LD_{50} > 4,952 mg/kg in Wistar rats exposed by gavage (no vehicle) (OECD 401, GLP-compliant) (Klimisch 1, reliable without restrictions) (Unpublished 2000, 003 WOE).
  - *Oral:* *Surrogate: Linseed oil (CAS #8001-26-1):* LD_{50} > 4,763 mg/kg in Wistar rats exposed by gavage (no vehicle) (OECD 401, GLP not specified) (Klimisch 1, reliable without restrictions) (Unpublished 1988, 004 WOE).
  - *Oral:* *Surrogate: Palm oil (CAS #8002-75-3):* LD_{50} > 5,000 mg/kg in rats (Klimisch 2, reliable with restrictions) (Unpublished 2000, 005 WOE).

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST-single) (Group II) Score (vH, H, M, or L): L
Hydrogenated olive oil was assigned a score of Low for systemic toxicity (single dose) based on a lack of effects on clinical signs, body weight, and gross pathology in acute oral toxicity studies conducted with the surrogates. GreenScreen® criteria classify chemicals as a Low hazard for systemic toxicity (single dose) when adequate data are available and negative for systemic toxicity up to acute oral doses of 2,000 mg/kg, and they are not GHS classified (CPA 2018b). The confidence in the score is high as it is based on measured data of high quality for strong surrogates. No reliable acute dermal or inhalation data were found.
- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.

- ECHA CHEM, CAS #84238-17-5, 2024b
    - *Oral*:
        - *Surrogate: Castor oil (CAS #8001-79-4):* In a GLP-compliant acute oral toxicity study conducted according to OECD Guideline 401 (GLP-compliant), 5 males and 5 females Wistar rats received undiluted castor oil at a single dose of 5 mL/kg via gavage (equivalent to 4,952 mg/kg). An observation period of 14 days followed. No mortalities or clinical signs of toxicity occurred during the study. Body weight development was normal, and there were no treatment related gross pathology abnormalities (Klimisch 1, reliable without restrictions) (Unpublished 2000, 003 WOE).
        - *Surrogate: Linseed oil (CAS #8001-26-1):* In an acute oral toxicity study conducted according to OECD Guideline 401 (GLP not specified), 5 males and 5 females Wistar rats received linseed oil at a single dose of 4,763 mg/kg via gavage. An observation period of 14 days followed. No clinical signs and no mortality were observed. There were no effects on gross pathology (Klimisch 1, reliable without restrictions) (Unpublished 1988, 004 WOE).

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST-repeat) (Group II*) Score (H, M, or L): L

Hydrogenated olive oil was assigned a score of Low for systemic toxicity (repeated dose) based on a lack of systemic toxicity at oral doses up to 17,000 mg/kg/day in subchronic repeated dose toxicity studies with the surrogates. GreenScreen® criteria classify chemicals as a Low hazard for systemic toxicity (repeated dose) when animal studies identify oral LOAEL values of >100 mg/kg/day established in 90-day studies. The confidence in the score is high as it is based on measured data of high quality for strong surrogates.

- Authoritative and Screening Lists
    - *Authoritative:* Not present on any authoritative lists for this endpoint.
    - *Screening:* Not present on any screening lists for this endpoint.
- ECHA CHEM, CAS #84238-17-5, 2024b, CIR 2000
    - *Oral:*
        - *Surrogate: Coconut oil (CAS #8001-31-8):* In a non-guideline, pre-GLP, repeated dose toxicity study, male and female Wistar rats were exposed to either coconut oil, oleo oil, butter fat, corn oil, or safflower oil in feed at 18.5% dietary fat (supplemented with up to 2.5% safflower oil to ensure adequacy of the essential fatty acids in all diets) for 47 weeks (15/sex/group). Body weight gain and food consumption were measured, fecal samples were collected and analyzed daily for fat absorption, and at specific intervals, blood and cholesterol were determined. At study termination, various organs (liver, kidneys, spleen, heart, adrenals, femurs, testes, and epididymal fat pads) were weighed, the liver and intestine were examined histologically, and total lipid, phospholipids, and cholesterol were examined in the liver. There were no significant findings in animals treated with coconut oil compared to the other dietary fats. Authors assigned the NOAEL at 18.5% in feed (Klimisch 2, reliable with restrictions) (Unpublished 1968, 001 WOE).
        - *Surrogate: Castor oil (CAS #8001-79-4):* In GLP-compliant repeated dose toxicity study performed equivalent or similar to OECD Guideline 408, male and female B6C3F1 mice were exposed to castor oil in feed at 0, 0.62, 1.25, 2.5, 5.0, or 10% for 90 days (10/sex/dose). Animals were evaluated based on body weight, food consumption, gross pathology, and histopathology (control and 10% groups).

Animals were also evaluated for sperm motility and morphology at necropsy and vaginal cytology. Liver weights were increased (severity not specified) in both sexes at 5 and 10%, and kidney weights were increased (severity not specified) in female mice at 5 and 10%; however, there were no corresponding histopathological findings, and no morphological changes in any organs. There were no significant findings based on the rest of the evaluated parameters. Authors assigned the NOAEL at 10% in feed, approximately 14,600 – 20,000 mg/kg/day based on actual food consumption and body weight data (Klimisch 2, reliable with restrictions) (Unpublished 1992, 003 WOE).

- *Surrogate: Castor oil (CAS #8001-79-4):* In GLP-compliant repeated dose toxicity study performed equivalent or similar to OECD Guideline 408, male and female F344 rats were exposed to castor oil in feed at 0, 0.62, 1.25, 2.5, 5.0, or 10% for 90 days (10/sex/dose). Animals were evaluated based on body weight, food consumption, hematology, clinical chemistry, gross pathology, and histopathology (control and 10% groups). Animals were also evaluated for sperm motility and morphology at necropsy and vaginal cytology. There were minor changes in some hematology and clinical chemistry parameters; however, there were no corresponding histopathological findings, and no morphological changes in any organs. There were no significant findings based on the rest of the evaluated parameters. Authors assigned the NOAEL at 10% in feed, approximately 5,800 mg/kg/day based on actual food consumption and body weight data (Klimisch 2, reliable with restrictions) (Unpublished 1992, 004 WOE).
- *Surrogate: Fully hydrogenated soybean oil (CAS not specified):* In a repeated dose toxicity study performed equivalent or similar to OECD Guideline 408 (GLP not specified), male and female Sprague-Dawley rats were exposed to feed containing fully hydrogenated soybean oil at 7.5% and 11.5% soybean oil as fat source, and control animals were exposed to 19% soybean oil, for 90 days (20/sex/dose). Animals were evaluated based on body weight, food consumption, hematology, clinical chemistry, urinalysis, gross pathology, and histopathology. There was a slight increase in mean caloric efficacy of the treatment group compared to the control group, which authors attributed to decreased absorption of the fully hydrogenated oil. There were no significant findings based on the rest of the evaluated parameters. Authors assigned the NOAEL at 7.5% in feed (Klimisch 2, reliable with restrictions) (Unpublished 1981, 005 WOE).
- *Surrogate: Crude palm oil (CAS #8002-75-3)*: In a repeated dose toxicity study, Wistar rats (15/sex/dose) were provided feed containing 10% crude palm oil for 91 days. The animals were evaluated for body weight, organs weight, hematology and gross pathology. No relevant effects were reported in the treated animals and authors established a NOAEL of 10% (9,200 mg/kg/day for males and 10,300 mg/kg/day for females[12]) (Klimisch 2, reliable with restrictions) (Unpublished 1991, 006 WOE).
- *Surrogate: Palm oil (CAS #8002-75-3):* In the previously described combined repeated dose and reproductive screening study, Sprague-Dawley rats (10 males, 20 females) were provided feed containing 15% heated or unheated palm oil (equivalent to 7,000 -17,000 mg/kg/day as calculated by ECHA dossier authors) for 10 weeks

[12] Males: 10% = 100,000 mg/kg feed * 0.092 kg feed / kg bw/day = 9,200 mg/kg/day ;
Females: 10% = 100,000 mg/kg feed * 0.103 kg feed / kg bw/day = 10,300 mg/kg/day (male and female subchronic Wistar rat food factor values http://www.tera.org/Tools/ratmousevalues.pdf).

prior to mating, and dams and offspring were maintained on the same diet after weaning. Offspring were examined at 5 weeks of age. The animals were evaluated for clinical signs of toxicity, body weight, food consumption, hematology, clinical chemistry, gross pathology, and histopathology. No relevant effects were found in the treated animals and a NOAEL of 15% was established (Klimisch score 2, reliable with restrictions) (Unpublished 1977, 007 WOE).

- *Surrogate: Pine nut oil (CAS #67701-30-8):* In a GLP-compliant repeated dose toxicity study performed according to OECD 408, Wistar rats (10/sex/dose) were given pine nut oil at 0, 1, 5, or 15% in feed for 98 days (females) or 100 days (males). No relevant effects were found in the treated animals and authors established a NOAEL of 15%, equivalent to 8,866 and 10, 242 mg/kg/day for males and females, respectively (Klimisch 1, reliable without restrictions) (Unpublished 2009, 008 WOE).

Neurotoxicity (single dose, N-single) (Group II) Score (vH, H, M, or L): *L*
Hydrogenated olive oil was assigned a score of Low for neurotoxicity (single dose) based on the lack of neurotoxic effects in acute oral toxicity studies conducted with surrogates at doses greater than the GHS guidance value for classification. GreenScreen® criteria classify chemicals as a Low hazard for neurotoxicity (single dose) when adequate negative data are available and they are not GHS classified (CPA 2018b). The confidence in the score is low as it is based on studies with limited neurotoxicity examination.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- ECHA CHEM, CAS #84238-17-5, 2024b
  - *Oral*:
    - *Surrogate: Castor oil (CAS #8001-79-4):* In the previously described GLP-compliant acute oral toxicity study conducted according to OECD Guideline 401, 5 males and 5 females Wistar rats received undiluted castor oil at a single dose of 5 mL/kg via gavage (equivalent to 4,952 mg/kg). An observation period of 14 days followed. No mortalities or clinical signs of neurotoxicity occurred during the study. Body weight development was normal, and there were no treatment related gross pathology abnormalities (Klimisch 1, reliable without restrictions) (Unpublished 2000, 003 WOE). *Clinical signs of neurotoxicity often evaluated in animal studies include: drowsiness, narcosis, reduced alertness, loss of reflexes, lack of coordination, irritability, fatigue, impaired memory function, deficits in perception and coordination, reaction time, or sleepiness, lethargy, and ataxia. If these effects are not transient in nature, then they shall be considered to support classification for Category 1 or 2 specific target organ toxicity single exposure. As animals in this study did not show any of these signs, ToxServices concluded that the test substance was not neurotoxic in this study.*
    - *Surrogate: Linseed oil (CAS #8001-26-1):* In the previously described acute oral toxicity study conducted according to OECD Guideline 401 (GLP not specified), 5 males and 5 females Wistar rats received linseed oil at a single dose of 4,763 mg/kg via gavage. An observation period of 14 days followed. No clinical signs and no mortality were observed. There were no effects on gross pathology (Klimisch 1, reliable without restrictions) (Unpublished 1988, 004 WOE).

Neurotoxicity (repeated dose, N-repeated) (Group II*) Score (H, M, or L): L
Hydrogenated olive oil was assigned a score of Low for neurotoxicity (repeated dose) based on a lack of neurological effects at oral doses up to 8,000 mg/kg/day in an OECD 408 study with the surrogate pine nut oil. GreenScreen® criteria classify chemicals as a Low hazard for neurotoxicity (repeated dose) when animal studies identify oral LOAEL values of >100 mg/kg/day established in 90-day studies and when they are not GHS classified (CPA 2018b). The confidence in the score is high as it is based on measured data of high quality for a strong surrogate.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- ECHA CHEM, CAS #84238-17-5, 2024b
  - *Surrogate: Pine nut oil (CAS #67701-30-8):* As previously summarized, in a GLP-compliant repeated dose toxicity study performed according to OECD 408, Wistar rats (10/sex/dose) were given pine nut oil at 0, 1, 5, or 15% in feed for 98 days (females) or 100 days (males). During Week 12, a functional observation battery was carried out on treated animals. No relevant effects were found in the treated animals and authors established a NOAEL of 15%, equivalent to 8,866 and 10, 242 mg/kg/day for males and females, respectively (Klimisch 1, reliable without restrictions) (Unpublished 2009, 008 WOE).

Skin Sensitization (SnS) (Group II*) Score (H, M, or L): *L*
Hydrogenated olive oil was assigned a score of Low for skin sensitization based on opinion of the CIR Expert Panel for plant-based fatty acid oils. Although limited animal studies on olive oil reported some positive responses, the test substance was 10 years old, and therefore, ToxServices did not weigh the positive results heavily. Additionally, human data on hydrogenated olive oil suggest low concerns for skin sensitization. GreenScreen® criteria classify chemicals as a Low hazard for skin sensitization when adequate data exist, and GHS classification is not warranted (CPA 2018b). The confidence in the score is low due to the limited data and conflicting results in the poor quality animal studies.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- CIR 2017

  Human data
  - The CIR Expert Panel reviewed a number of clinical studies on plant-derived fatty acid oils and did not identify concerns for skin sensitization.
  - Hydrogenated olive oil was not sensitizing to the skin in a human repeated insult patch test (HRIPT) when applied at 12% in a lipstick under occlusion in 108 subjects (no further details provided).
  - *Surrogate: Hydrogenated olive oil unsaponifiables (CAS not specified):* Hydrogenated olive oil unsaponifiables was not sensitizing in a HRIPT when applied to the face and neck at 2% under occlusion to 50 subjects (no further details provided).
  - *Surrogate: Olive oil unsaponifiables (CAS not specified):* Olive oil unsaponifiables was not sensitizing in a HRIPT when applied in a bath and body mist at 2.5% under semi-occlusion to 107 subjects (no further details provided).
  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not sensitizing in a HRIPT when applied in a scalp conditioner/hair wax at 0.1595% (applied neat) under occlusion to 104 subjects (no further details provided).
  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not sensitizing in a HRIPT when applied in a scalp conditioner at 0.7% (diluted to 1%) under occlusion to 110 subjects (no further

details provided).

- *Surrogate: Olive oil (8001-25-0):* Olive oil was not sensitizing in a HRIPT when applied in a body lotion at 1.6% (applied at 0.02 mL) under occlusion to 110 subjects. One participant had a slight erythema following the seventh patch that did no reoccur, no other reactions were observed (no further details provided).
- *Surrogate: Olive oil (8001-25-0):* Olive oil was not sensitizing in a HRIPT when applied in a skin salve at 10% (applied neat) under occlusion to 209 subjects (no further details provided).
- *Surrogate: Olive oil (8001-25-0):* Olive oil was not sensitizing in a HRIPT when applied in a body moisturizer at 22% under semi-occlusion to 105 subjects (no further details provided).
- *Surrogate: Olive oil (8001-25-0):* Olive oil was not sensitizing in a HRIPT when applied in a conditioning hair oil at 58.7% under semi-occlusion to 102 subjects (no further details provided).
- *Surrogate: Olive oil (8001-25-0):* Olive oil was not sensitizing in a HRIPT when applied in a foundation (makeup) at 69.6% under occlusion in 200 µL to 209 subjects (no further details provided).
- *Surrogate: Olive oil unsaponifiables (CAS not specified):* Olive oil unsaponifiables was not sensitizing in a HRIPT when applied in a skin cleansing product at 5% (based on a 10% dilution of the product) under semi-occlusion to 57 subjects (no further details provided).
- *Surrogate: Olive oil (8001-25-0):* Olive oil was not a primary skin irritant when applied in a scalp conditioner at 0.7% (diluted to 1%) in 114 subjects (no further details provided).
- *Surrogate: Olive oil unsaponifiables (CAS not specified):* Olive oil unsaponifiables was not irritating when applied at 2.5% in a bath body mist, 150 µL, under semi-occlusion to 107 subjects (no further details provided).

Animal data

- *Surrogate: Olive oil (CAS #8001-25-0):* Single drops of USP-grade olive oil that had been stored in its original metal container for 10 years were applied to 12 guinea pigs on a clipped area of the back every 2-to-6 weeks for 5 months. Four guinea pigs were similarly treated with store-bought virgin olive oil. Although no animals had a positive reaction following the first application, 11 of 12 had a positive reaction at some point. Two animals had a single positive response, and 2 died by week 16. In the group exposed to virgin olive oil, 1 of 4 animals had a positive reaction at week 2, and 1 of 4 had a positive reaction at weeks 4 and 6.
- *Surrogate: Olive oil (CAS #8001-25-0):* Twenty two Guinea pigs sensitive to the 10-year-old USP grade olive oil were evaluated for cross-reactivity to store-bought olive oil (virgin not specified), corn oil, and peanut oil. All 5 oils were applied simultaneously to the backs. Eighteen of 22 animals had a positive reaction to each type of olive oil, although it was not the same 18 animals for all cases. There were no cross-reactivities observed with the corn or peanut oils.
- *Surrogate: Olive oil (CAS #8001-25-0):* 8 Sensitized, and 4 non-sensitized guinea pigs were exposed to a single drop of the unsaponifiable fraction of the 10-year-old oil. All of the sensitized animals reacted to the unsaponifiable fraction, whereas the non-sensitized animals did not.

Respiratory Sensitization (SnR) (Group II*) Score (H, M, or L): *L*

Hydrogenated olive oil was assigned a score of Low for respiratory sensitization based on extrapolation from negative skin sensitization data combined with a lack of structural alerts for respiratory sensitization. GreenScreen® criteria classify chemicals as a low hazard for respiratory sensitization

when adequate data exist and GHS classification is not warranted (CPA 2018b). The confidence in the score is low as this rationale does not cover respiratory hypersensitivity caused by non-immunological mechanisms, for which human experience is the main evidence of activity.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- OECD 2024
  - Based on its default structure, hydrogenated olive oil does not contain any structural alerts for respiratory sensitization (Appendix E).
- No data were identified for the target compound for this endpoint. Therefore, ToxServices evaluated the respiratory sensitization potential of hydrogenated olive oil according to ECHA's guideline (ECHA 2017), which states that the mechanisms leading to respiratory sensitization are essentially similar to those leading to skin sensitization (ECHA 2017). ECHA recommended that if a chemical is not a dermal sensitizer based on high quality data, it is unlikely to be a respiratory sensitizer. ECHA also noted that this rationale does not cover respiratory hypersensitivity caused by non-immunological mechanisms, for which human experience is the main evidence of activity (ECHA 2017). Hydrogenated olive oil is not expected to be a skin sensitizer based on surrogate data. In addition, it does not contain structural alerts for respiratory sensitization. Therefore, it is unlikely to be a respiratory sensitizer, and a score of Low was assigned.

Skin Irritation/Corrosivity (IrS) (Group II) Score (vH, H, M, or L): L

Hydrogenated olive oil was assigned a score of Low for skin irritation/corrosivity based on numerous studies in humans exposed to hydrogenated olive oil, and the surrogates olive oil and olive oil unsaponifiables at concentrations up to 69.6% and at most minimal irritation, not warranting classification, in rabbit studies with the undiluted surrogate palm oil. GreenScreen® criteria classify chemicals as a Low hazard for skin irritation/corrosivity when adequate data exist and GHS classification is not warranted (CPA 2018b). The confidence in the score is high based on consistently negative results in numerous studies.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- CIR 2017

  Human data
  - Hydrogenated olive oil was not irritating to the skin in a human repeated insult patch test (HRIPT) when applied at 12% in a lipstick under occlusion in 108 subjects (no further details provided).
  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not a primary skin irritant when applied in a scalp conditioner at 0.7% (diluted to 1%) in 114 subjects (no further details provided).
  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not irritating in a HRIPT when applied in a scalp conditioner/hair wax at 0.1595% (applied neat) under occlusion to 104 subjects (no further details provided).
  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not irritating in a HRIPT when applied in a scalp conditioner at 0.7% (diluted to 1%) under occlusion to 110 subjects (no further details provided).
  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not irritating in a HRIPT when applied in a body lotion at 1.6% (applied at 0.02 mL) under occlusion to 110 subjects. One participant had a slight erythema following the seventh patch that did no reoccur, no other reactions were observed (no further details provided).

  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not irritating in a HRIPT when applied in a body moisturizer at 22% under semi-occlusion to 105 subjects (no further details provided).
  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not irritating in a HRIPT when applied in a conditioning hair oil at 58.7% under semi-occlusion to 102 subjects (no further details provided).
  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not irritating in a HRIPT when applied in a foundation (makeup) at 69.6% under occlusion in 200 µL to 209 subjects (no further details provided).
  - *Surrogate: Olive oil (8001-25-0):* Olive oil was not irritating when applied at 10% in a skin salve applied to the lips, hands, nails, elbows, knees, feet, and heels for 4 weeks in 51 subjects. 2 participants had very slight erythema on the lips, 5 on the elbows, lips, or knees, and 15 reported subjective irritation (no further details provided).
  - *Surrogate: Olive oil unsaponifiables (CAS not specified):* Olive oil unsaponifiables was not irritating when applied at 2.5% in a bath body mist, 150 µL, under semi-occlusion to 107 subjects (no further details provided).
  - *Surrogate: Olive oil unsaponifiables (CAS not specified):* Olive oil unsaponifiables was not irritating in a HRIPT when applied in a skin cleansing product at 5% (based on a 10% dilution of the product) under semi-occlusion to 57 subjects (no further details provided).
- CIR 2000
  - *Surrogate: Palm oil (CAS #8002-75-3):* In dermal irritation study, nine rabbits (strain and sex not specified) were administered undiluted pam oil to the skin (presumably intact) for 24 hours under occlusion. At 24 hours, the primary irritation index was 0.22/8 and the authors concluded the substance was "practically nonirritating".
  - *Surrogate: Palm oil (CAS #8002-75-3):* In another dermal irritation test following the same protocol as above, 6/9 rabbits had scores of 1 at two hours after application, and 4/9 had scores of 1 at 24 hours after application. The primary irritation index was 0.67/8 and the authors concluded the substance was "minimally irritating".

Eye Irritation/Corrosivity (IrE) (Group II) Score (vH, H, M, or L): L

Hydrogenated olive oil was assigned a score of Low for eye irritation/corrosivity based on the lack of ocular irritation effects sufficient to warrant classification in animal studies with the surrogate palm oil. GreenScreen® criteria classify chemicals as a Low hazard for eye irritation/corrosivity when adequate and negative data are available, and when they are not GHS classified (CPA 2018b). The confidence in the score is high based on measured data for a strong surrogate.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- CIR 2017
  - Numerous fatty acid oils were evaluated for eye irritation, including coconut oil, palm oil, cottonseed oil, rice bran oil, rice germ oil, sweet almond oil, sesame seed oil, and what germ oil. The studies were non-guideline, and most test substances were nonirritating to mildly irritating, and the only exceptions occurred with 1.5% palm oil in a lotion, and with linseed oil at 9.4% in a mascara (the rest of the ingredients in the lotion and mascara were not reported).
- CIR 2000
  - *Surrogate: Palm oil (CAS #8002-75-3):* In an ocular irritation study, six rabbits (strain and sex not specified) were administered ocular instillations of undiluted palm oil. The eyes were scored using the Draize scale (0-110). The total ocular irritation score was 3 on day

one after instillation and reduced at day 2-post instillation. All reactions were cleared by day 3. The study authors concluded that undiluted palm oil was slightly irritating to the rabbit eye.

- *Surrogate: Palm oil (CAS #8002-75-3):* In another ocular irritation test, two different hand creams containing 2.0% palm oil were slightly irritating to the rabbit eye.

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M, or L): L

Hydrogenated olive oil was assigned a score of Low for acute aquatic toxicity based on the expected lack of toxicity at saturation supported by measured LC_{50}/EC_{50} > 100 mg/L in fish, daphnia, and algae for the surrogates. GreenScreen® criteria classify chemicals as a Low hazard for acute aquatic toxicity when no acute aquatic toxicity is detected at the water solubility limit and when they L/EC_{50} values are > 100 mg/L (CPA 2018b). The confidence in the score is high as it is based on measured data of high quality for strong surrogates for all three trophic levels.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- ECHA CHEM, CAS #84238-17-5, 2024b

  Fish
  - *Surrogate: Castor oil (CAS #8001-79-4):* 96-hour LC_{50} (*Danio rerio*, zebra fish) = 1,000 mg/L nominal, static conditions (GLP-compliant, OECD Guideline 203) (Klimisch score 2, reliable with restrictions) (Unpublished 1988, 002 WOE).
  - *Surrogate: Linseed oil (CAS #8001-26-1):* 96-hour LC_{50} (*D. rerio*, zebra fish) = 1,000 mg/L nominal, static conditions (GLP unspecified, OECD Guideline 203) (Klimisch score 2, reliable with restrictions) (Unpublished 1988, 003 WOE).
  - *Surrogate: Fatty acids, palm oil, hydrogenated (CAS #84238-17-5):* 48-hour LC_{50} (*Leuciscus idus melatonus,* Golden orfe) = 1,000 mg/L nominal, static conditions (GLP-compliant, OECD Guideline 203) (Klimisch score 2, reliable with restrictions) (Unpublished 2001, 005 WOE).

  Invertebrates
  - *Surrogate: Palm oil (CAS #8002-75-3):* 48-hour EL_{50} (*Acartia tonsa,* marine invertebrate) > 1,000 mg/L nominal (3,200 mg/L WAF in Tween 80), static conditions (non-GLP, method not specified) (Klimisch score 2, reliable with restrictions) (Unpublished 1998, 002 WOE).
  - *Surrogate: Crude soybean oil (CAS not specified):* 48-hour EL_{50} (*Acartia tonsa,* marine invertebrate) based on immobility > 1,000 mg/L nominal, static conditions (GLP not specified, ISO 14669, ISO 10253, and GESAMP guidelines) (Klimisch score 2, reliable with restrictions) (Unpublished 2002, 003 WOE).
  - *Surrogate: Crude palm oil (CAS #8002-75-3):* 48-hour EL_{50} (*Acartia tonsa,* marine invertebrate) based on immobility > 1,000 mg/L nominal, static conditions (GLP not specified, ISO 14669, ISO 10253, and GESAMP guidelines) (Klimisch score 2, reliable with restrictions) (Unpublished 2002, 005WOE).

  Algae
  - *Surrogate: Crude Palm oil (CAS #8002-75-3):* 72-hour EC_{50} (*Skeletonema costatum,* algae) > 1,000 mg/L nominal for growth rate static conditions (GLP not specified, ISO 14669, ISO 10253, and GESAMP guidelines) (Klimisch score 2, reliable with restrictions) (Unpublished 2002, 002 WOE).
  - *Surrogate: Crude soybean oil (CAS not specified):* 72-hour EC_{50} (*Skeletonema costatum,*

algae) > 1,000 mg/L nominal for growth rate static conditions (GLP not specified, ISO 14669, ISO 10253, and GESAMP guidelines) (Klimisch score 2, reliable with restrictions) (Unpublished 2002, 003 WOE).

Chronic Aquatic Toxicity (CA) Score (vH, H, M, or L): *L*

Hydrogenated olive oil was assigned a score of Low for chronic aquatic toxicity based on expected lack of toxicity at saturation. GreenScreen® criteria classify chemicals as a Low hazard for chronic aquatic toxicity when chronic aquatic toxicity values are > 10 mg/L (CPA 2018b). The confidence in the score is low due to the lack of measured data.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- U.S. EPA 2022
  - Using the representative structure for triglyceride of oleic acid (glyceryl trioleate, CAS #122-32-7), which has the same SMILES notation as tallow (CAS #61789-97-7), ECOSAR assigned this structure to the Esters and Neutral Organics chemical classes. Chronic toxicity values (ChVs) in fish, daphnia and algae were estimated to be 10 times greater than the predicted water solubility of 2.5E-20 mg/L. The ChVs values ranged from 5.5E-17 to 4.3E-11 mg/L. In addition, the estimated log K_{ow} of 23.291 according to ECOSAR (or 18.75 according to U.S. EPA 2017) is higher than the log K_{ow} cutoff of 8 for all trophic levels, indicating a lack of effects at saturation in water (See Appendix F).

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): L

Hydrogenated olive oil was assigned a score of Low for persistence based on its surrogate being readily degradable in a well conducted test meeting the GHS rapid degradability criteria. Although EPI Suite™ predicts that the target chemical is not readily biodegradable, surrogate data carry more weight than predicted data as the surrogate is very similar in structure to the target. GreenScreen™ criteria classify chemicals as a Low hazard for persistence when data indicate they mainly partition to soil, sediment or water and meet the GHS rapid degradability criteria (CPA 2018b). The confidence in the score is high as it is based on measured data of high quality for a strong surrogate.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- ECHA CHEM, CAS #84238-17-5, 2024b
  - *Surrogate: fatty acids, palm-oil, hydrogenated (CAS #84238-17-5):* The substance is not expected to persist in the environment because unbranched fatty acids and glycerides are readily broken down by gram positive and gram negative bacteria, fungi, yeasts, and algae.
  - *Surrogate: Hydrogenated coconut oil (CAS #84836-98-6):* A GLP-compliant ready biodegradability test conducted according to OECD 301 F (Manometric Respirometry Test) was performed with domestic activated sludge (adaptation not specified) exposed to the test substance for 28 days under aerobic conditions. Biodegradation was measured based on oxygen consumption. Biodegradation was reported to be 65% after day 1 based on oxygen consumption, 65% on day 28 based on nitrification, and they reported it did not meet the 10-day window. The reference substance, sodium benzoate, provided the expected results. (Klimisch score 2, reliable with restrictions) (Unpublished 2010, 005 WOE).

  - *Surrogate: Castor oil (CAS #8001-79-4):* A GLP-compliant ready biodegradability test conducted according to European Economic Communities (1984) Method for the determination of ecotoxicity at level 1, Biodegradation, Repetitive Die Away Test (DG XI/400/84. Rev.1). The test substance was added to domestic, non-adapted, activated sludge at 7.5 g/L. Biodegradation was measured based on oxygen consumption over 42 days. The degree of degradation was 50% after one week, increasing to 62% during the second week. The substance was considered readily biodegradable and the reference substance (sodium acetate) provided the expected results (Klimisch score 2, reliable with restrictions) (Unpublished 1988, 003 WOE).
  - *Surrogate: Low erucic acid rapeseed oil (CAS #8002-12-9):* A ready biodegradability test conducted according to EC L-33-T-82 (1982) (Method published by the Coordinating European Council, now listed as CEC L-33-A-934) (non-GLP). The test substance was added to domestic, non-adapted, activated sludge (amount not specified). Biodegradation was measured based on disappearance of ethylene units, measured with infrared spectrophotometer, over 21 days. The degree of degradation was 87.5-96.8% at 7 days, and 91.8-97.5% at 21 days. The substance was considered readily biodegradable. Results of the reference substance (di-isotridecyl-adipate) were not provided (Klimisch score 2, reliable with restrictions) (Unpublished 1989, 004 WOE).
- U.S. EPA 2017
  - Based on its default structure, the BIOWIN modeling Ready Biodegradable Predictor indicates that hydrogenated olive oil is expected to undergo primary degradation within days, and ultimate degradation within weeks-to-months, and will not be readily biodegradable. Fugacity modeling (EQC default method) predicts 69.8% will partition to sediment with a half-life of 337.5 days (8.1e+003/24 hours), 28.3% will partition to soil with a half-life of 75 days (1.8e+003/24 hours), and 1.9% will partition to water with a half-life of 37.5 days (900 hours/24 hours/day) (Appendix D).
- Based on weight of evidence, a score of Low was assigned. Plant based oils are known to be degradable numerous microorganisms in the environment, and available biodegradation data on the surrogates indicate that these ingredients are readily biodegradable meeting the GHS criteria for rapid biodegradability (biotic or abiotic degradation of > 70% in the aquatic environment in 28 days under environmentally realistic conditions), which correspond to a GreenScreen® score of Low. The EPI Suite™ predicts that the target chemical is not readily biodegradable and has a half-life of 337.5 days in the major compartment, sediment, which corresponds to a GreenScreen® score of Very High. However, surrogate data carry more weight than predicted data as the surrogate is very similar in structure to the target. Accordingly, ToxServices relied on the surrogate data and assigned a score of Low for this endpoint.

Bioaccumulation (B) Score (vH, H, M, L, or vL): *vL*
Hydrogenated olive oil was assigned a score of Very Low for bioaccumulation based on a predicted BAF of 0.893. GreenScreen® criteria classify chemicals as a Very Low hazard for bioaccumulation when the BCF/BAF is ≤ 100 (CPA 2018b). The confidence in the score is low due to lack of measured data.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- U.S. EPA 2017
  - Based on its default structure, BCFBAF predicts a BAF of 0.893 using the Arnot-Gobas model for the upper trophic level, taking metabolism into consideration based on a predicted

log K_{ow} of 23.29 (Appendix D).

- Based on the weight of evidence, a score of Very Low was assigned. Although the predicted log K_{ow} of 23.29 for the target chemical corresponds to a GreenScreen® score of Very High, such a high log K_{ow} indicates that the substance is not bioavailable (and log K_{ow} is difficult to measure experimentally). According to GHS (UN 2023), BCF/BAF values are preferred over log K_{ow} values to determine bioaccumulation potential. Therefore, ToxServices relied on the predicted BAF to score this endpoint.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M, or L): *L*

Hydrogenated olive oil was assigned a score of Low for reactivity based on lack of structural alerts for oxidizing and explosive properties, and lack of reactivity warnings on the safety data sheet. GreenScreen® criteria classify chemicals as a Low hazard for reactivity when available data indicate that the chemical does not warrant GHS classification for any of the reactivity sub-endpoints and the chemical is not present on authoritative or screening lists (CPA 2018b). The confidence in the score is low due to lack of measured data.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- No measured data were identified. Therefore, screening procedures for explosivity were used here to estimate the reactivity property of hydrogenated olive oil. These procedures are listed in the GHS (UN 2023).
  - Based on its default structure, hydrogenated olive oil is not considered explosive or self-reactive due to lack of functional groups associated with explosive or self-reactive properties (See Appendix G).
  - Based on its default structure, hydrogenated olive oil is not considered to have oxidizing properties as it does not contain any structural groups known to be correlated with a tendency to react exothermally with combustible materials.
- Hallstar Italia srl 2015
  - A safety data sheet for hydrogenated olive oil does not identify any reactivity hazards.

Flammability (F) Score (vH, H, M, or L): L

Hydrogenated olive oil was assigned a score of Low based on surrogate data. The surrogate hydrogenated soybean oil has an HMIS flammability rating of 1 – not flammable, and a flash point > 500°F (> 260 °C), and the surrogate olive oil has a smoke point of ≥ 350 °F, implying a flash point well above 350°F; these data correspond to GHS Not Classified. GreenScreen® criteria classify chemicals as a Low hazard for flammability GHS classification is not warranted (CPA 2018b). Confidence in the score is high based on measured data for strong surrogates.

- Authoritative and Screening Lists
  - *Authoritative:* Not present on any authoritative lists for this endpoint.
  - *Screening:* Not present on any screening lists for this endpoint.
- Hallstar Italia srl 2015
  - A safety data sheet for hydrogenated olive oil does not identify a flammability hazard.
- Ag Processing Inc. 2018
  - A safety data sheet for hydrogenated (low I.V.) soybean oil, CAS #8016-70-4, indicates a flammability hazard of 1 from HMIS ("Materials that must be preheated before ignition will occur. Includes liquids, solids and semi solids having a flash point above 200 °F (93 °C)")

and NFPA ("Materials that must be preheated to burn"). The SDS also reports a flash point of > 500°F (> 260°C).

- Eckelkamp 2021
    - Olive oil has a smoke point of 350 to 410°F.

Use of New Approach Methodologies (NAMs)[13] in the Assessment, Including Uncertainty Analyses of Input and Output

New Approach Methodologies (NAMs) used in this GreenScreen® include lack of experimental data and no relevant test method for the endpoint respiratory sensitization, and limitations associated with the use of *in vitro* test methods to assess genotoxicity. NAMs are non-animal alternative that can be used alone or in combination to provide information for safety assessment (Madden et al. 2020). At present, there is not a uniformly accepted framework on how to report and apply individual NAMs (U.S. EPA 2020, OECD 2020). The expanded application of NAMs greatly amplifies the need to communicate uncertainties associated with their use. As defined by EFSA (2018), uncertainty is "a general term referring to all types of limitations in available knowledge that affect the range and probability of possible answers to an assessment question." The quality, utility, and accuracy of NAM predictions are greatly influenced by two primary types of uncertainties (OECD 2020):

- Type I: Uncertainties related to the input data used
- Type II: Uncertainties related to extrapolations made

As shown in Table 5, Type I (input data) uncertainties in hydrogenated olive oil's NAMs dataset include lack of experimental data and no validated test methods to assess respiratory sensitization. Hydrogenated olive oil's Type II (extrapolation output) uncertainties include use of *in vitro* data to assess genotoxicity, which does not fully mimic *in vivo* metabolism. Some of hydrogenated olive oil's type II uncertainties were alleviated by the use of *in vitro* test batteries and/or in combination of *in vivo* data.

Table 5: Summary of NAMs Used in the GreenScreen® Assessment, Including Uncertainty Analyses

Uncertainty Analyses (OECD 2020)	
Type I Uncertainty: Data/Model Input	**Respiratory sensitization**: No experimental data are available and there are no validated test methods.
Type II Uncertainty: Extrapolation Output	**Genotoxicity:** The bacterial reverse mutation assay (as defined in OECD Guideline 471) only tests point-mutation inducing activity in non-mammalian cells, and the exogenous metabolic activation system does not entirely mimic *in vivo* conditions[14]. The *in vitro* chromosome aberration assay (OECD Guideline 473) does not measure aneuploidy and it only measures structural chromosomal aberrations. The exogenous metabolic activation system does not entirely mirror *in vivo* metabolism[15].

[13] NAMs refers to any non-animal technology, methodology, approach, or combination thereof that inform chemical hazard and risk assessments. NAMs include *in silico*/computational tools, *in vitro* biological profiling (e.g., cell cultures, 2,3-D organotypic culture systems, genomics/transcriptomics, organs on a chip), and frameworks (i.e., adverse outcome pathways (AOPs), defined approaches (DA), integrated approaches to testing and assessment (IATA).
[14] https://www.oecd-ilibrary.org/docserver/9789264071247-en.pdf?expires=1614097593&id=id&accname=guest&checksum=89925F80B9F4BD2FFC6E90F94A0EE427
[15] https://www.oecd-ilibrary.org/docserver/9789264264649-en.pdf?expires=1614098015&id=id&accname=guest&checksum=6A4F9CE52EA974F5A74793DD54D54352

	The *in vitro* SCE assay (as defined in OECD Guideline 479, a guideline deleted in 2014) detects reciprocal exchange of DNA without providing the underlying mechanism of action[16]. **Respiratory sensitization**: The OECD Toolbox only identifies structural alerts, and does not define applicability domains. Additionally, the ECHA guidance (2017), on which the use of OECD Toolbox structural alerts is based, does not evaluate non-immunologic mechanisms for respiratory sensitization.	
Endpoint	**NAMs Data Available and Evaluated? (Y/N)**	**Types of NAMs Data (*in silico* modeling/*in vitro* biological profiling/frameworks)**
Carcinogenicity	N	
Mutagenicity	Y	*In vitro* data: bacterial mutagenicity, chromosome aberration, and SCE assays.
Reproductive toxicity	N	
Developmental toxicity	N	
Endocrine activity	N	
Acute mammalian toxicity	N	
Single exposure systemic toxicity	N	
Repeated exposure systemic toxicity	N	
Single exposure neurotoxicity	N	
Repeated exposure neurotoxicity	N	
Skin sensitization	N	
Respiratory sensitization	Y	*In silico* modeling: OECD Toolbox structural alerts
Skin irritation	N	
Eye irritation	N	
Acute aquatic toxicity	N	
Chronic aquatic toxicity	Y	*In silico* modeling: ECOSAR
Persistence	N/A	
Bioaccumulation	Y	*In silico* modeling: EPI Suite™ *In vitro* data: OECD Guideline 301 ready biodegradation tests

[16] https://www.oecd.org/env/ehs/testing/Draft_Intro_Genotoxicity%20TGs%20September%202014.pdf

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APPENDIX A: Hazard Classification Acronyms
(in alphabetical order)

(AA) Acute Aquatic Toxicity

(AT) Acute Mammalian Toxicity

(B) Bioaccumulation

(C) Carcinogenicity

(CA) Chronic Aquatic Toxicity

(D) Developmental Toxicity

(E) Endocrine Activity

(F) Flammability

(IrE) Eye Irritation/Corrosivity

(IrS) Skin Irritation/Corrosivity

(M) Mutagenicity and Genotoxicity

(N) Neurotoxicity

(P) Persistence

(R) Reproductive Toxicity

(Rx) Reactivity

(SnS) Sensitization- Skin

(SnR) Sensitization- Respiratory

(ST) Systemic/Organ Toxicity

APPENDIX B: Results of Automated GreenScreen® Score Calculation for Hydrogenated Olive Oil (CAS #226993-75-5)

TOXSERVICES
TOXICOLOGY RISK ASSESSMENT CONSULTING

GreenScreen® Score Inspector

Table 1: Hazard Table

			Group I Human					Group II and II* Human								Ecotox		Fate		Physical	
			Carcinogenicity	Mutagenicity/Genotoxicity	Reproductive Toxicity	Developmental Toxicity	Endocrine Activity	Acute Toxicity	Systemic Toxicity		Neurotoxicity		Skin Sensitization*	Respiratory Sensitization*	Skin Irritation	Eye Irritation	Acute Aquatic Toxicity	Chronic Aquatic Toxicity	Persistence	Bioaccumulation	Reactivity	Flammability
Table 2: Chemical Details									S	R *	S	R *	*	*								
Inorganic Chemical?	Chemical Name	CAS#	C	M	R	D	E	AT	STs	STr	Ns	Nr	SNS*	SNR*	IrS	IrE	AA	CA	P	B	Rx	F
No	Hydrogentated Olive Oil	226993-75-5	L	L	L	L	DG	L	L	L	*L*	L	*L*	*L*	L	L	L	*L*	L	*vL*	*L*	L

Table 3: Hazard Summary Table

Benchmark	a	b	c	d	e	f	g
1	No	No	No	No	No		
2	No	No	No	No	No	No	No
3	No	No	No	No			
4	STOP						

Table 4

Chemical Name	Preliminary GreenScreen® Benchmark Score
Hydrogentated Olive Oil	4

Note: Chemical has not undergone a data gap assessment. Not a Final GreenScreen™ Score

Table 6

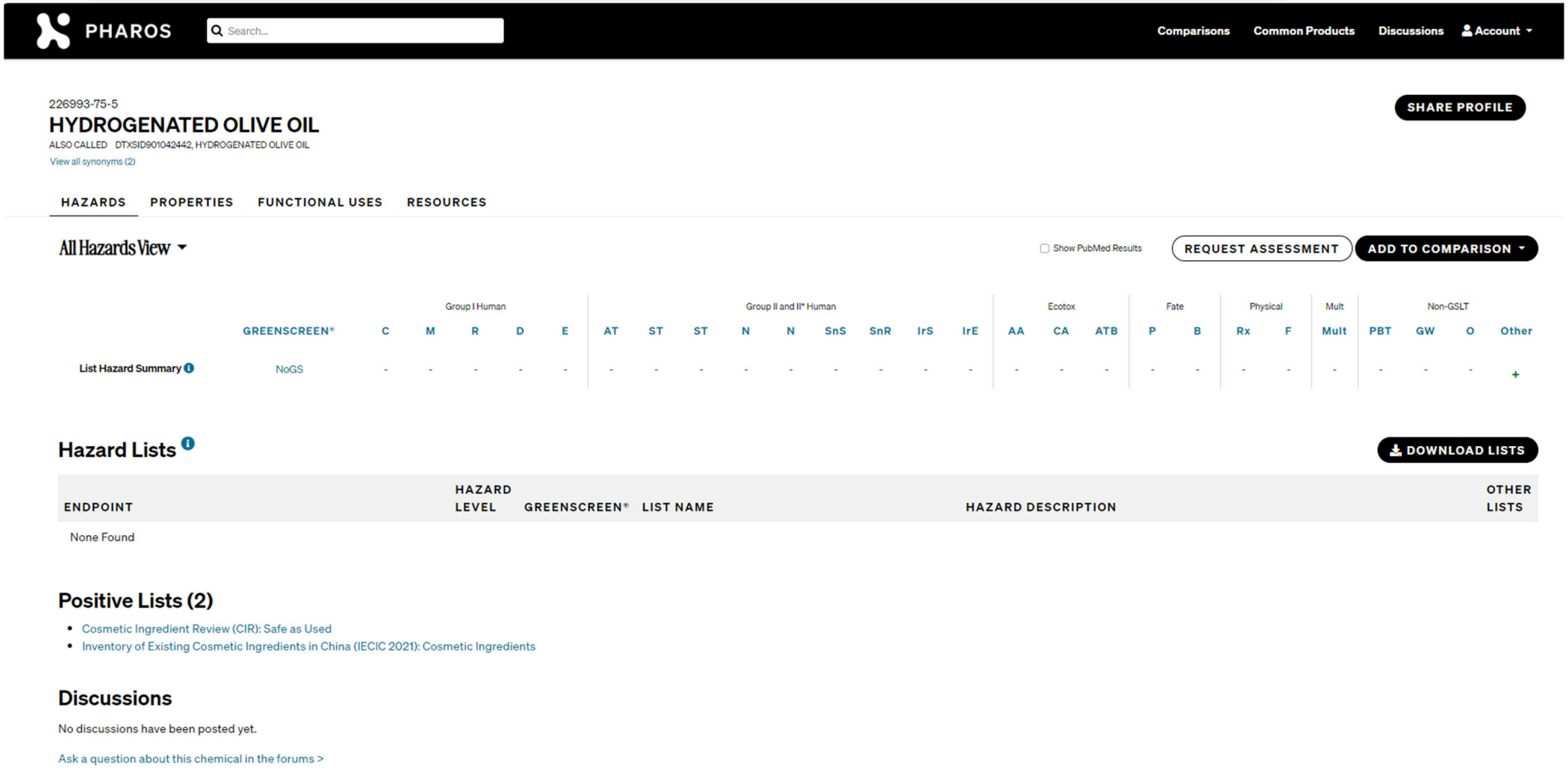
Chemical Name	Final GreenScreen® Benchmark Score
Hydrogentated Olive Oil	3DG

After Data gap Assessment
Note: No Data gap Assessment Done if Preliminary GS Benchmark Score is 1.

Table 5: Data Gap Assessment Table

Datagap Criteria	a	b	c	d	e	f	g	h	i	j	bm4	End Result
1												
2												
3												
4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	3DG

APPENDIX C: Pharos Output for Hydrogenated Olive Oil (CAS #226993-75-5)



PHAROS Search... Comparisons Common Products Discussions Account

226993-75-5

HYDROGENATED OLIVE OIL

ALSO CALLED DTXSID901042442, HYDROGENATED OLIVE OIL

View all synonyms (2)

SHARE PROFILE

HAZARDS PROPERTIES FUNCTIONAL USES RESOURCES

All Hazards View

Show PubMed Results REQUEST ASSESSMENT ADD TO COMPARISON

		Group I Human					Group II and II* Human									Ecotox			Fate		Physical		Mult	Non-GSLT			
	GREENSCREEN®	C	M	R	D	E	AT	ST	ST	N	N	SnS	SnR	IrS	IrE	AA	CA	ATB	P	B	Rx	F	Mult	PBT	GW	O	Other
List Hazard Summary	NoGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+

Hazard Lists

DOWNLOAD LISTS

ENDPOINT	HAZARD LEVEL	GREENSCREEN®	LIST NAME	HAZARD DESCRIPTION	OTHER LISTS
None Found					

Positive Lists (2)

- Cosmetic Ingredient Review (CIR): Safe as Used
- Inventory of Existing Cosmetic Ingredients in China (IECIC 2021): Cosmetic Ingredients

Discussions

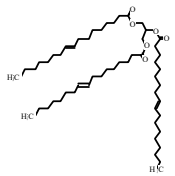
No discussions have been posted yet.

Ask a question about this chemical in the forums >

APPENDIX D: EPI Suite™ Modeling Results for Hydrogenated Olive Oil (CAS #226993-75-5)

(Estimated values included in the GreenScreen® are highlighted and bolded)

EPI Suite Results For CAS 226993-75-5



```
SMILES : CCCCCCCCC=CCCCCCCCC(=O)OCC(OC(=O)CCCCCCCC=CCCCCCCCC)COC(=O)CCCCCCCC=C
CCCCCCCC
CHEM   : Representative structure
MOL FOR: C57 H104 O6
MOL WT : 885.46
----------------------------- EPI SUMMARY (v4.11) --------------------------
Henry LC (atm-m3/mole) :   ------
Log Kow (octanol-water):   ------
Boiling Point (deg C)  :   ------
Water Solubility (mg/L):   ------
Physical Property Inputs:
Vapor Pressure (mm Hg) :   ------
Melting Point (deg C)  :   ------

Log Octanol-Water Partition Coef (SRC):
```

```
Log Kow (KOWWIN v1.69 estimate) =  23.29

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPVP v1.43):
Boiling Pt (deg C):  829.24  (Adapted Stein & Brown method)
Melting Pt (deg C):  349.84  (Mean or Weighted MP)
VP(mm Hg,25 deg C):  1E-020  (Modified Grain method)
VP (Pa, 25 deg C) :  1.34E-018  (Modified Grain method)
Subcooled liquid VP: 5.15E-017 mm Hg (25 deg C, Mod-Grain method)
: 6.86E-015 Pa (25 deg C, Mod-Grain method)

Water Solubility Estimate from Log Kow (WSKOW v1.42):
Water Solubility at 25 deg C (mg/L):  2.551e-020
log Kow used: 23.29 (estimated)
no-melting pt equation used

Water Sol Estimate from Fragments:
Wat Sol (v1.01 est) =  8.8546e-007 mg/L

ECOSAR Class Program (ECOSAR v1.11):
Class(es) found:
Esters

Henrys Law Constant (25 deg C) [HENRYWIN v3.20]:
Bond Method :   9.61E-004  atm-m3/mole  (9.73E+001 Pa-m3/mole)
Group Method:   1.47E-005  atm-m3/mole  (1.49E+000 Pa-m3/mole)
For Henry LC Comparison Purposes:
User-Entered Henry LC:  not entered
Henrys LC [via VP/WSol estimate using User-Entered or Estimated values]:
HLC:  4.567E+004 atm-m3/mole  (4.628E+009 Pa-m3/mole)
VP:   1E-015 mm Hg (source: MPBPVP)
WS:   2.55E-020 mg/L (source: WSKOWWIN)

Log Octanol-Air Partition Coefficient (25 deg C) [KOAWIN v1.10]:
Log Kow used:  23.29  (KowWin est)
Log Kaw used:  -1.406  (HenryWin est)
Log Koa (KOAWIN v1.10 estimate):  24.696
Log Koa (experimental database):  None

Probability of Rapid Biodegradation (BIOWIN v4.10):
Biowin1 (Linear Model)         :   1.1738
Biowin2 (Non-Linear Model)     :   0.9997
```

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Expert Survey Biodegradation Results:
Biowin3 (Ultimate Survey Model):   2.5581  (weeks-months)
Biowin4 (Primary Survey Model) :   4.0643  (days        )
MITI Biodegradation Probability:
Biowin5 (MITI Linear Model)    :   0.9970
Biowin6 (MITI Non-Linear Model):   0.7801
Anaerobic Biodegradation Probability:
Biowin7 (Anaerobic Linear Model):  0.6963
Ready Biodegradability Prediction:   NO

Hydrocarbon Biodegradation (BioHCwin v1.01):
Structure incompatible with current estimation method!

Sorption to aerosols (25 Dec C)[AEROWIN v1.00]:
Vapor pressure (liquid/subcooled):  6.87E-015 Pa (5.15E-017 mm Hg)
Log Koa (Koawin est  ): 24.696
Kp (particle/gas partition coef. (m3/ug)):
Mackay model           :  4.37E+008
Octanol/air (Koa) model:  1.22E+012
Fraction sorbed to airborne particulates (phi):
Junge-Pankow model     :  1
Mackay model           :  1
Octanol/air (Koa) model:  1

Atmospheric Oxidation (25 deg C) [AopWin v1.92]:
Hydroxyl Radicals Reaction:
OVERALL OH Rate Constant = 231.8733 E-12 cm3/molecule-sec [Cis-isomer]
OVERALL OH Rate Constant = 254.6733 E-12 cm3/molecule-sec [Trans-isomer]
Half-Life =    0.554 Hrs (12-hr day; 1.5E6 OH/cm3) [Cis-isomer]
Half-Life =    0.504 Hrs (12-hr day; 1.5E6 OH/cm3) [Trans-isomer]
Ozone Reaction:
OVERALL Ozone Rate Constant =    39.000000 E-17 cm3/molecule-sec [Cis-]
OVERALL Ozone Rate Constant =    60.000000 E-17 cm3/molecule-sec [Trans-]
Half-Life =     0.705 Hrs (at 7E11 mol/cm3) [Cis-isomer]
Half-Life =     0.458 Hrs (at 7E11 mol/cm3) [Trans-isomer]
Reaction With Nitrate Radicals May Be Important!
Fraction sorbed to airborne particulates (phi):
1 (Junge-Pankow, Mackay avg)
1 (Koa method)
Note: the sorbed fraction may be resistant to atmospheric oxidation
```

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Soil Adsorption Coefficient (KOCWIN v2.00):
Koc    :  1E+010  L/kg (MCI method)
Log Koc:  14.181      (MCI method)
Koc    :  4.746E+013  L/kg (Kow method)
Log Koc:  13.676      (Kow method)

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v2.00]:
Total Kb for pH > 8 at 25 deg C :  1.455E-001  L/mol-sec
Kb Half-Life at pH 8:      55.135  days
Kb Half-Life at pH 7:       1.510  years
(Total Kb applies only to esters, carbmates, alkyl halides)

Bioaccumulation Estimates (BCFBAF v3.01):
Log BCF from regression-based method = 0.500 (BCF = 3.162 L/kg wet-wt)
Log Biotransformation Half-life (HL) = 3.3727 days (HL = 2359 days)
Log BCF Arnot-Gobas method (upper trophic) = -0.049 (BCF = 0.893)
Log BAF Arnot-Gobas method (upper trophic) = -0.049 (BAF = 0.893)
log Kow used: 23.29 (estimated)

Volatilization from Water:
Henry LC:  1.47E-005 atm-m3/mole  (estimated by Group SAR Method)
Half-Life from Model River:      121.6  hours   (5.065 days)
Half-Life from Model Lake :       1576  hours   (65.65 days)

Removal In Wastewater Treatment:
Total removal:              94.04  percent
Total biodegradation:        0.78  percent
Total sludge adsorption:    93.26  percent
Total to Air:                0.00  percent
(using 10000 hr Bio P,A,S)

Level III Fugacity Model: (MCI Method)
** Note: When the Log Kow is > 7, the model may be underestimating
the mass of material in sediment and overestimating the mass of
material in the water column (biota). Consider using the results
of the default EQC model. **

Mass Amount    Half-Life    Emissions
(percent)        (hr)       (kg/hr)
Air       0.0189          0.431        1000
Water     17.7            900          1000
```

```
Soil       82.3            1.8e+003     1000
Sediment   1.08e-009       8.1e+003     0
Persistence Time: 1.07e+003 hr

Level III Fugacity Model: (MCI Method with Water percents)
Mass Amount    Half-Life    Emissions
(percent)        (hr)       (kg/hr)
Air        0.0189          0.431        1000
Water      17.7            900          1000
water      (1.81e-015)
biota      (17.7)
suspended sediment (2.72e-011)
Soil       82.3            1.8e+003     1000
Sediment   1.08e-009       8.1e+003     0
Persistence Time: 1.07e+003 hr

Level III Fugacity Model: (EQC Default)
Mass Amount    Half-Life    Emissions
(percent)        (hr)       (kg/hr)
Air        0.00649         0.431        1000
Water      1.9             900          1000
water      (1.46e-017)
biota      (0.143)
suspended sediment (1.75)
Soil       28.3            1.8e+003     1000
Sediment   69.8            8.1e+003     0
Persistence Time: 3.11e+003 hr
```

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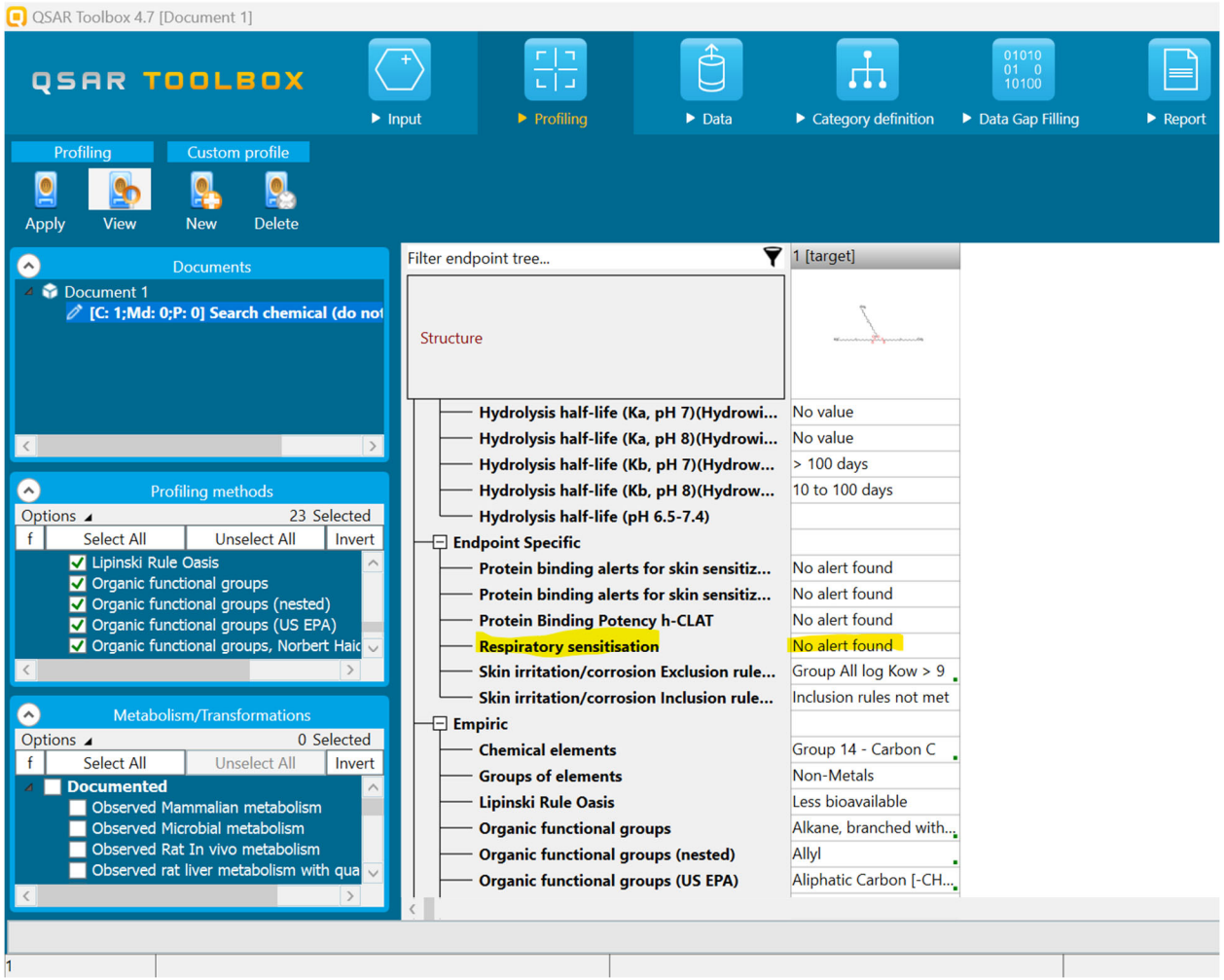
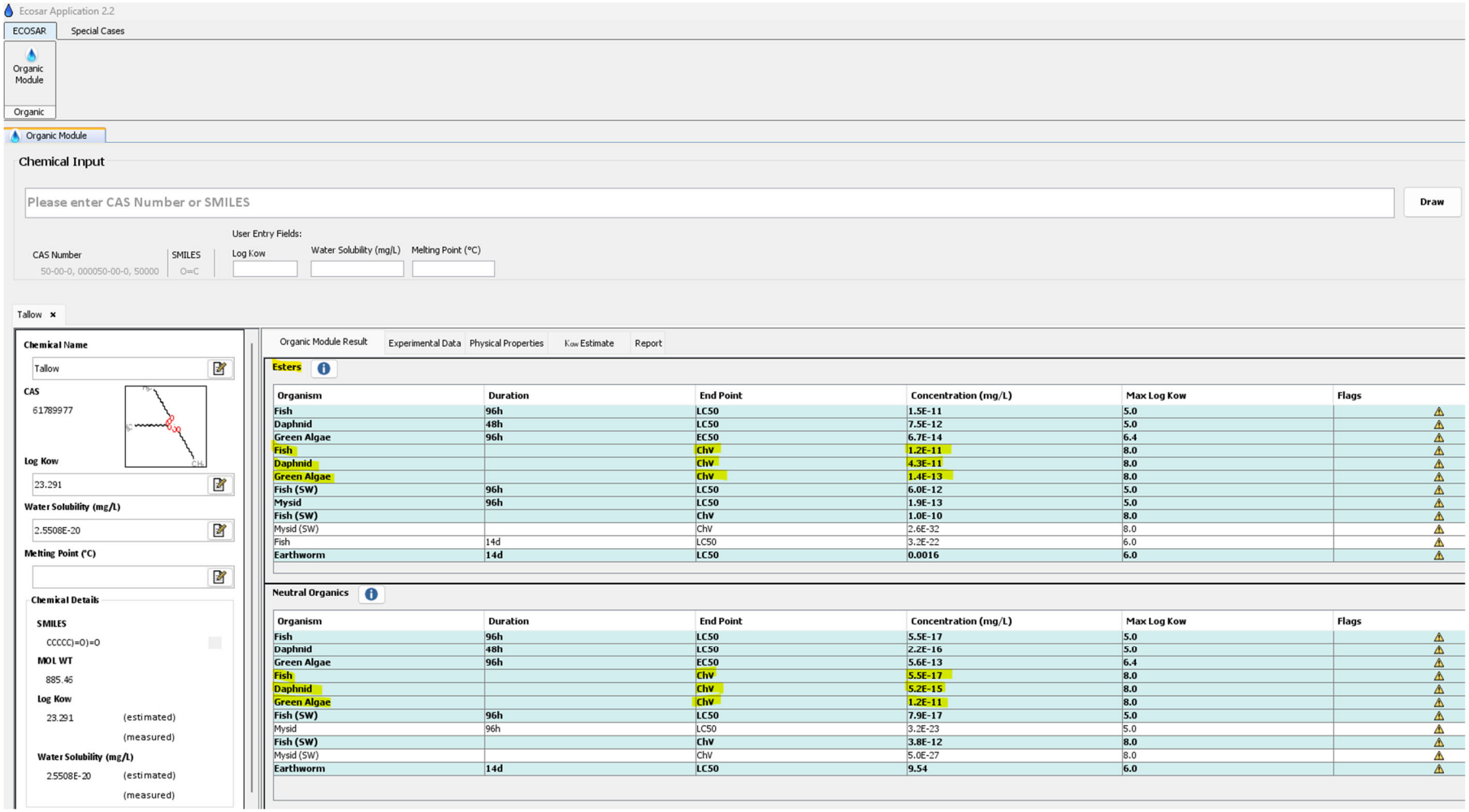
APPENDIX E: OECD Toolbox Profiling Results for Hydrogenated Olive Oil (CAS #226993-75-5)

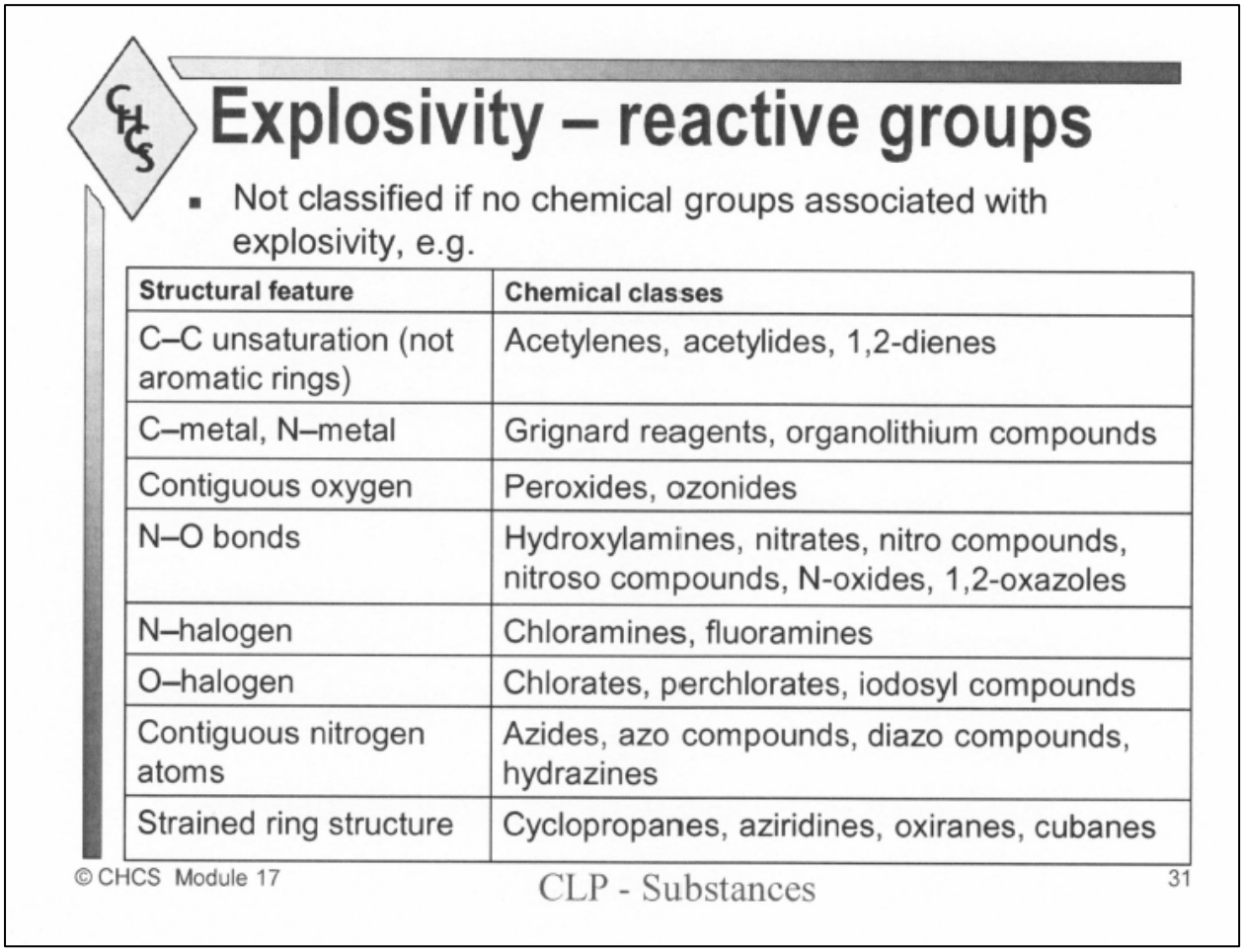


APPENDIX F: ECOSAR Modeling Results for Hydrogenated Olive Oil (CAS #226993-75-5)



APPENDIX G: Known Structural Alerts for Reactivity

Explosivity – Abbreviated List



Explosivity – reactive groups

- Not classified if no chemical groups associated with explosivity, e.g.

Structural feature	Chemical classes
C–C unsaturation (not aromatic rings)	Acetylenes, acetylides, 1,2-dienes
C–metal, N–metal	Grignard reagents, organolithium compounds
Contiguous oxygen	Peroxides, ozonides
N–O bonds	Hydroxylamines, nitrates, nitro compounds, nitroso compounds, N-oxides, 1,2-oxazoles
N–halogen	Chloramines, fluoramines
O–halogen	Chlorates, perchlorates, iodosyl compounds
Contiguous nitrogen atoms	Azides, azo compounds, diazo compounds, hydrazines
Strained ring structure	Cyclopropanes, aziridines, oxiranes, cubanes

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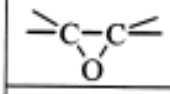
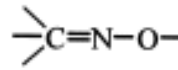
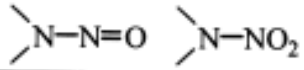
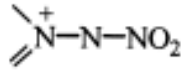
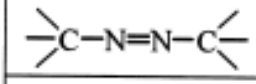
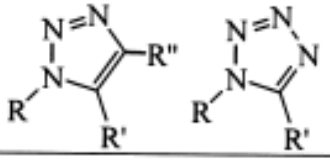
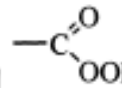
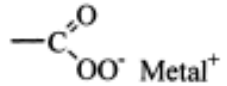
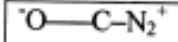
Explosivity – Full List

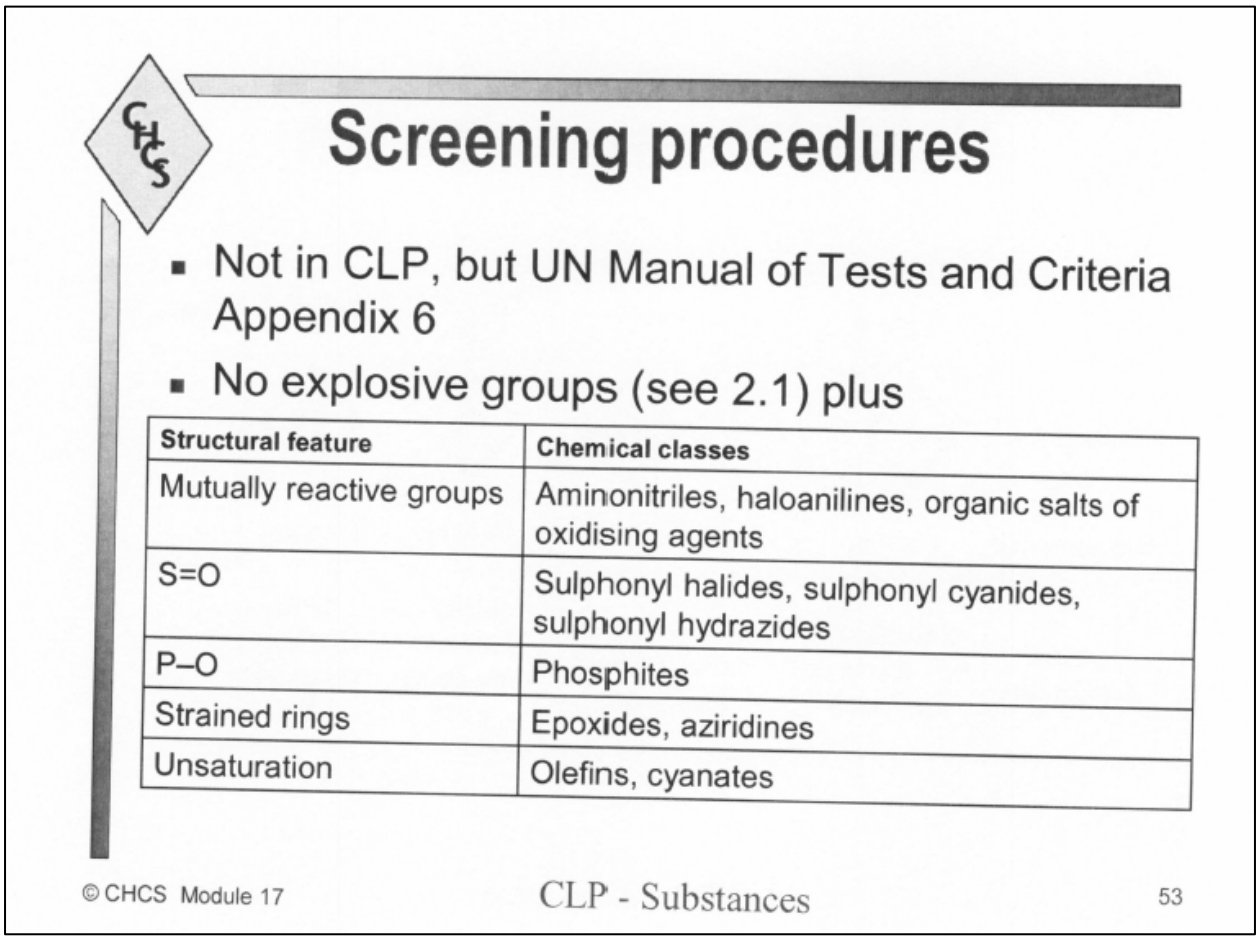
Table R.7.1-28 Chemical groups associated with explosive properties

Chemical group	Chemical Class
-C≡C- -C≡C-Metal -C≡C-Halogen	Acetylenic Compounds Metal Acetylides Haloacetylene Derivatives
	Diazo Compounds
-N=O -NO_2	Nitroso and Nitro Compounds,
R-O-N=O R-O-NO_2	Acyl or Alkyl Nitrites and Nitrates
	1,2-Epoxides
	Metal Fulminates or *aci*-Nitro Salts
	N-Metal Derivatives (especially heavy metals)
	N-Nitroso and N-Nitro Compounds
	N-Azolium Nitroimidates
	Azo Compounds
Ar-N=N-O-Ar	Arene Diazoates
$(ArN=N)_2O$, $(ArN=N)_2S$	Bis-Arenediazo Oxides and Sulfides
RN=N-NR'R''	Triazines
	High-nitrogen Compounds: e.g. Triazoles, Tetrazoles

Chemical group	Chemical Class
[1] ROOR', [2] 	Peroxy Compounds: [1] Alkyl hydroperoxides (R'=H), Peroxides (R'=organic); [2] Peroxo acids (R'=H), Peroxyesters (R'=organic)
[1] ROOMetal, [2] 	Metal peroxides, Peroxoacids salts
$-N_3$	Azides e.g. PbN_6, CH_3N_3
	Arenediazonium oxides i.e. inner diazonium salts in which the counter ion is an oxide
Ar-N=N-S- Ar-N=N-S-Ar	Diazonium sulfides and derivatives, Arenediazo Aryl Sulfides
XO_n	Halogen Oxide: e.g. percholrates, bromates, etc
NX_3 e.g. $NC1_3$, $RNC1_2$	N-Halogen Compounds

Adapted from Bretherick (Bretherick's Handbook of Reactive Chemical Hazards 6th Ed., 1999, Butterworths, London)

Self-Reactive Substances



Screening procedures

- Not in CLP, but UN Manual of Tests and Criteria Appendix 6
- No explosive groups (see 2.1) plus

Structural feature	Chemical classes
Mutually reactive groups	Aminonitriles, haloanilines, organic salts of oxidising agents
S=O	Sulphonyl halides, sulphonyl cyanides, sulphonyl hydrazides
P–O	Phosphites
Strained rings	Epoxides, aziridines
Unsaturation	Olefins, cyanates

APPENDIX H: Change in Benchmark Score

Table 6 provides a summary of changes to the GreenScreen® Benchmark™ for hydrogenated olive oil. The GreenScreen® Benchmark Score for hydrogenated olive oil has not previously been determined.

Table 6: Change in GreenScreen® Benchmark™ for Hydrogenated Olive Oil

Date	GreenScreen® Benchmark™	GreenScreen® Version	Comment
December 4, 2024	BM-3_{DG}	v. 1.4	Original GreenScreen® assessment.

Licensed GreenScreen® Profilers

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