

Section 1: Identification of the substance/mixture and of the company/undertaking

Product identifier

Name of the substance	Alpha - pinene
Trade name of the substance	SYLVAPINE™ 402
Identification Number	80-56-8
Registration number	01-2119519223-49-0001
Product registration number	Not available.
Synonyms	None.
SDS number	6486/4493E
Product code	2000969, 2000970
Date of first issue	14-March-2012
Version number	2.0
Revision date	17-April-2012
Supersedes date	12-April-2012

Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Industrial uses: Uses of substances as such or in preparations at industrial sites. Formulation [mixing] of preparations and/or re-packaging (excluding alloys). Intermediate.
Uses advised against	None known.

Details of the supplier of the safety data sheet

Supplier

Company name	Arizona Chemical B.V.
Address	Transistorstraat 16 1322 CE Almere NL
Telephone	+31 36 546 2800
e-mail	regulatory.EU@azchem.com
Contact person	Not available.
Emergency telephone number	EU NCEC +44 1865 407 333

Section 2: Hazards identification

Classification of the substance or mixture

The substance has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Classification R10, Xn;R22-65, Xi;R38, R43

The full text for all R-phrases is displayed in section 16.

Classification according to Regulation (EC) No 1272/2008 as amended

Physical hazards

Flammable liquids	Category 3	H226 - Flammable liquid and vapour.
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Health hazards

Skin corrosion/irritation	Category 2	H315 - Causes skin irritation.
Skin sensitisation	Category 1	H317 - May cause an allergic skin reaction.
Aspiration hazard	Category 1	H304 - May be fatal if swallowed and enters airways.

Hazard summary

Physical hazards	Flammable.
Health hazards	Harmful if swallowed. Irritating to skin. May cause sensitization by skin contact. Harmful: may cause lung damage if swallowed.
Environmental hazards	Not classified for hazards to the environment.
Specific hazards	May cause sensitization by skin contact.
Main symptoms	Sensitisation. Irritant effects.

Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains:	Alpha - pinene
Identification Number	80-56-8



Signal word	Danger
Hazard statements	H226 - Flammable liquid and vapour. H304 - May be fatal if swallowed and enters airways. H315 - Causes skin irritation. H317 - May cause an allergic skin reaction.

Precautionary statements

Prevention	P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response	P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P331 - Do NOT induce vomiting. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.
Storage	Not available.
Disposal	P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label information Not applicable.

Other hazards Not assigned.

Section 3: Composition/information on ingredients

Substance

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Alpha - pinene	100	80-56-8 201-291-9	01-2119519223-49-0001	-	
Classification:	DSD: R10, Xn;R65, Xi;R38, R43				
	CLP: Flam. Liq. 3;H226, Asp. Tox. 1;H304, Skin Irrit. 2;H315, Skin Sens. 1;H317				

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

#: This substance has workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

Section 4: First aid measures

General information

If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Take off immediately all contaminated clothing. Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation occurs: Get medical advice/attention.

Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control centre immediately. Rinse mouth. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Aspiration may cause pulmonary oedema and pneumonitis.
Most important symptoms and effects, both acute and delayed	Irritant effects. May cause allergic skin reaction.
Indication of any immediate medical attention and special treatment needed	Not available.

Section 5: Firefighting measures

General fire hazards	Flammable liquid and vapour.
Extinguishing media	
Suitable extinguishing media	Water spray, dry chemical, carbon dioxide.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Special hazards arising from the substance or mixture	Upon decomposition, this product emits carbon monoxide, carbon dioxide and/or low molecular weight hydrocarbons.
Advice for firefighters	
Special protective equipment for firefighters	Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. Structural firefighters protective clothing will only provide limited protection.
Special firefighting procedures	In case of fire and/or explosion do not breathe fumes. Wear suitable protective equipment. Move containers from fire area if you can do so without risk.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. Do not touch or walk through spilled material. Keep people away from and upwind of spill/leak. Ventilate closed spaces before entering them.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.
Environmental precautions	Prevent further leakage or spillage if safe to do so.
Methods and material for containment and cleaning up	ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep combustibles (wood, paper, oil etc) away from spilled material. Large Spills: Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb spillage with non-combustible, absorbent material. Following product recovery, flush area with water. Small Spills: Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use.
Reference to other sections	For waste disposal, see section 13. See Section 8 for personal protective equipment.

Section 7: Handling and storage

Precautions for safe handling	Observe good industrial hygiene practices. Follow all MSDS/label precautions even after container is emptied because they may retain product residues. DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not smoke. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use non-sparking tools and explosion-proof equipment. Avoid contact with skin. Avoid contact with eyes. Avoid prolonged exposure. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Keep away from heat, sparks and open flame. Keep containers closed when not in use. Store locked up. Store in cool place. Store at ambient temperature and atmospheric pressure. Store in a well-ventilated place. Keep container tightly closed. Keep in an area equipped with sprinklers. Keep out of the reach of children.
Specific end use(s)	Not available.

Section 8: Exposure controls/personal protection

Control parameters

Occupational exposure limits No exposure limits noted for the ingredient(s).

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Not available.

DNEL

Components	Type	Route	Value	Form
Alpha - pinene (80-56-8)	General Population	Dermal	81 ug/cm ²	Local;Acute;
		Inhalation	1.06 mg/m ³	Systemic toxicity.; Chronic;
		Oral	0.31 mg/kg/day	Systemic toxicity.; Chronic;
	Workers	Inhalation	5.98 mg/m ³	Local; Chronic;
		Dermal	161 ug/cm ²	Local;Acute;

PNEC

Components	Type	Route	Value	Form
Alpha - pinene (80-56-8)	Not applicable	Sea water	0.4 µg/l	
		Soil	0.539 mg/kg/dw	
		Oral	1.35 mg/kg/food	
		Sewage Treatment Plant	3.26 mg/l	
		Sediment	1.033 mg/kg/dw	Fresh water
		Sediment	0.103 mg/kg/dw	Sea water
		Fresh water	4 µg/l	

Exposure controls

Appropriate engineering controls Explosion-proof general and local exhaust ventilation.

Individual protection measures, such as personal protective equipment

General information Not available.

Eye/face protection Safety glasses. Wear eye/face protection.

Skin protection

- Hand protection Wear protective gloves.

- Other Not available.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Thermal hazards Not available.

Hygiene measures

When using, do not eat, drink or smoke. Avoid contact with eyes. Avoid contact with skin. Contaminated work clothing should not be allowed out of the workplace. Handle in accordance with good industrial hygiene and safety practices. Eye wash fountain and emergency showers are recommended. Launder contaminated clothing before reuse.

Environmental exposure controls Not available.

Section 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance Liquid.

Physical state Liquid.

Form Liquid.

Colour Colourless.

Odour Characteristic.

Odour threshold Not available.

pH Not applicable.

Melting point/freezing point -55 °C (-67 °F)

Boiling point, initial boiling point, and boiling range	156 °C (312.8 °F) at 101.325 kPa
Flash point	31 °C (88 °F) at 1013 hPa
Auto-ignition temperature	255 °C (491 °F) at 1013 hPa
Flammability (solid, gas)	Not available.
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Oxidising properties	Not applicable.
Explosive properties	Not applicable.
Explosive limit	Not applicable.
Vapour pressure	690 hPa estimated 690 Pa at 20°C
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Density	859 kg/m ³ at 20°C
Solubility (water)	< 0.04 mg/l at 20°C
Partition coefficient (n-octanol/water)	4.49 at 25°C
Decomposition temperature	Not available.
Viscosity	1.3 mPa·s at 25°C
Percent volatile	99.9 % estimated
Other data	
Chemical family	Terpene
Explosivity	> 0.8 % Explosive limits in air, lower, % by volume
Flammability	Flammable
Flammability class	OSHA Class IC
Miscible (water)	Immiscible
Molecular weight	136.23 g/mol
Weighted solids	0 %
Other information	No relevant additional information available.

Section 10: Stability and reactivity

Reactivity	None known.
Chemical stability	Risk of ignition. Material is stable under normal conditions.
Possibility of hazardous reactions	Not available.
Conditions to avoid	Strong oxidizing agents. Heat, flames and sparks. Avoid temperatures exceeding the flash point.
Incompatible materials	This product may react with strong oxidizing agents.
Hazardous decomposition products	Upon decomposition this product emits acrid dense smoke with carbon dioxide, carbon monoxide, water and other products of combustion.

Section 11: Toxicological information

General information	Not available.
Information on likely routes of exposure	
Ingestion	May be fatal if swallowed and enters airways.
Inhalation	May be fatal if swallowed and enters airways.
Skin contact	Causes skin irritation.
Eye contact	Not available.
Symptoms	Not available.
Information on toxicological effects	
Acute toxicity	May be fatal if swallowed and enters airways.

Components

Alpha - pinene (80-56-8)

Test results

Acute Dermal LD50 New Zealand white rabbit: > 2000 mg/kg
Data is for similar product.

Acute Oral LD50 Wistar rat: 3700 mg/kg Data is for similar product.

Subacute Inhalation LOAEL Fischer 344 rat: > 25 ppm 14 weeks male;Data is for similar product.; OECD 413

Subacute Inhalation NOAEL Fischer 344 rat: > 200 ppm 14 weeks female;Data is for similar product.; OECD 413

Subacute Oral NOAEL Mouse: > 50 ppm 14 weeks OECD 413

Subacute Oral NOAEL Sprague-Dawley rat: 250 mg/kg/day
No toxicity to reproduction; Data is for similar product.; OECD 414

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation

Causes skin irritation.

Product

SYLVAPINE™ 402

Test results

Irritation Corrosion - Skin
Result: positive
Species: Human
Organ: Skin
Comments: Skin irritation.
Notes: ECVAM v1.8

Serious eye damage/eye irritation

Not classified.

Product

SYLVAPINE™ 402

Test results

Irritation Corrosion - Eye
Result: negative
Species: New Zealand white rabbit
Organ: Eye
Observation Period: 72 hr
Comments: No eye irritation.; Data is for similar product.
Notes: OECD 405

Respiratory sensitisation Not available.

Skin sensitisation

May cause sensitization by skin contact.

Product

SYLVAPINE™ 402

Test results

29 % Local Lymph Node Assay - Lowest Concentration
Producing Reaction
Result: positive
Species: Mouse
Organ: Skin
Comments: May cause sensitization by skin contact.; Data is for similar product.
Notes: OECD 429

Germ cell mutagenicity

Not classified.

Product

SYLVAPINE™ 402

Test results

Genetic Toxicity - in Vivo
Result: negative
Species: Mouse
Comments: Data is for similar product.
Notes: OECD 474

Germ Cell Mutagenicity: Ames
Result: negative
Species: Salmonella typhimurium
Comments: No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.; Data is for similar product.
Notes: OECD 471

Germ cell mutagenicity

Not classified.

Product

SYLVAPINE™ 402

Test results

Germ Cell Mutagenicity: Chromosome Abberation
Result: negative
Species: Human
Comments: This material is considered to be non-clastogenic to human lymphocytes in vitro.; Data is for similar product.
Notes: OECD 473

In vitro gene mutation study in mammalian cells
Result: negative
Species: Mouse
Comments: Data is for similar product.
Notes: OECD 476

Unscheduled DNA Synthesis in Mammalian Cells in Vitro
Result: negative
Species: Sprague-Dawley Rat
Organ: Hepatocytes
Comments: No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.;
Notes: OECD 482

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Carcinogenicity Not available.

Reproductive toxicity Not available.

Specific target organ toxicity - single exposure Not available.

Specific target organ toxicity - repeated exposure Not available.

Aspiration hazard May be fatal if swallowed and enters airways.

Mixture versus substance information Not available.

Other information Not available.

Section 12: Ecological information

Toxicity

Components

Alpha - pinene (80-56-8)

Test results

EC10 Activated sewage sludge: 38 mg/l 3 hr Data is for similar product.; OEDC 209

EC50 Activated sewage sludge: 326 mg/l 3 hr Data is for similar product.; OEDC 209

EC50 Algae (Pseudokirchneriella subcapitata): 48 hr >> Water solubility; Data is for similar product.; OECD 201

EC50 Daphnia: 48 hr >> Water solubility; Data is for similar product.; OECD 202

LC50 Carp (Cyprinus carpio): 96 hr >> Water solubility; Data is for similar product.; OEDC 203

NOEC Algae (Pseudokirchneriella subcapitata): 48 hr >> Water solubility; Data is for similar product.; OECD 201

NOEC Carp (Cyprinus carpio): 96 hr >> Water solubility; Data is for similar product.; OECD 203

NOEC Daphnia: 48 hr >> Water solubility; Data is for similar product.; OECD 202

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

The product is biodegradable.

Product

SYLVAPINE™ 402

Test results

76 %
Result: Readily biodegradable
Species: Activated sewage sludge
Test Duration: 28 d
Comments: Data is for similar product.

Bioaccumulative potential Not available.

Mobility The product is insoluble in water.

Environmental fate - Partition coefficient Not available.

Mobility in soil Not available.

Results of PBT and vPvB assessment Not available.

Other adverse effects Not available.

Section 13: Disposal considerations

Waste treatment methods

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 14: Transport information

ADR

UN number UN2368
UN proper shipping name alpha-PINENE
Transport hazard class(es) 3
Subsidiary class(es) -
Packing group III
Environmental hazards No
Special precautions for user Not available.

RID

UN number UN2368
UN proper shipping name alpha-PINENE
Transport hazard class(es) 3
Subsidiary class(es) -
Packing group III
Environmental hazards No
Special precautions for user Not available.

ADN

UN number UN2368
UN proper shipping name alpha-PINENE
Transport hazard class(es) 3
Subsidiary class(es) -
Packing group III
Environmental hazards No
Special precautions for user Not available.

IATA

UN number UN2368
UN proper shipping name alpha-Pinene
Transport hazard class(es) 3
Subsidiary class(es) -
Packing group III
Environmental hazards No
Special precautions for user Not available.

IMDG

UN number UN2368
UN proper shipping name alpha-PINENE
Transport hazard class(es) 3
Subsidiary class(es) -
Packing group III
Marine pollutant No
Special precautions for user Not available.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulations

Regulation (EC) No. 2037/2000 on substances that deplete the ozone layer

Not regulated.

Regulation (EC) No. 2037/2000 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 on persistent organic pollutants, Annex I

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals

Not regulated.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3

Not listed.

Regulation (EC) No. 689/2008 Import and export of dangerous chemicals

Not regulated.

Commission Decision 2000/479/EC on the implementation of a European pollutant emission register (EPER)

Not listed.

Regulation (EC) No. 1907/2006, Article 59(1). Candidate List

Not listed.

Regulation (EC) No. 1907/2006 Annex XIV Substance subject to autorisation

Not regulated.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Young people under 18 years old are not allow to work with this product according to the EU Directive 94/33/EC on the protection of young people at work.

Chemical safety assessment

A Chemical Safety Assessment has been carried out for this substance.

Water hazard class

VwVws WGK1

Section 16: Other information

List of abbreviations Not available.

References Not available.

Information on evaluation method leading to the classification of mixture Not available.

Full text of any statements or R-phrases and H-phrases under Sections 2 to 15

R10 Flammable.
R22 Harmful if swallowed.
R38 Irritating to skin.
R43 May cause sensitization by skin contact.
R65 Harmful: may cause lung damage if swallowed.
H226 - Flammable liquid and vapour.
H304 - May be fatal if swallowed and enters airways.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.

Revision information

Section 5: Firefighting measures: Suitable extinguishing media
Section 9: Physical and chemical properties: Odour
Section 11: Toxicological information: Acute toxicity
Section 12: Ecological information: Persistence and degradability
Section 13: Disposal considerations: Disposal methods/information

Training information

Not available.

Disclaimer

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SDS sections updated

Section 5: Firefighting measures: Suitable extinguishing media
Section 9: Physical and chemical properties: Odour
Section 11: Toxicological information: Acute toxicity
Section 12: Ecological information: Persistence and degradability
Section 13: Disposal considerations: Disposal methods/information

Alpha-pinene – Use and Exposure scenarios :

Use and exposure annex to the Safety Data Sheet for the substance known as Alpha-pinene.

Note to the reader: Should your use and exposure scenario not be featured here – please contact the supplier (details on page 1 of the SDS)

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1. Substance identity

EC number:	201-291-9
EC name:	pin-2(3)-ene
CAS number (EC inventory):	80-56-8
IUPAC name:	2,6,6-trimethylbicyclo[3.1.1]hept-2-ene
Molecular formula:	C ₁₀ H ₁₆
Molecular weight range:	136.234

Exposure Scenarios.

ES 1. Users by workers in industrial settings: Exposure Scenario for the manufacturing stage (synthesis of substance being registered). (Referred to as Exposure scenario No. 1 in CSR)

Process category (PROC):

- PROC 1: Use in closed process, no likelihood of exposure
- PROC 2: Use in closed, continuous process with occasional controlled exposure
- PROC 3: Use in closed batch process (synthesis or formulation)
- PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises
- PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
- PROC 15: Use as laboratory reagent

Environmental release category (ERC):

- ERC 1: Manufacture of substances

Subsequent service life relevant for that use?: no

Exposure Assessment

9. EXPOSURE ASSESSMENT (extracted from CSR)

9.1 Manufacture of the substance (Industrial Application)

9.1.1 Exposure Scenario : Manufacture of the substance (Industrial Application)

Section 1	Exposure Scenario Title
Title	Manufacture of the substance (Industrial Application) CAS: 80-56-8
Use Descriptor	Sector of Use: SU 3 Industrial Uses.
	Process Categories: PROC1, PROC2, PROC3, PROC4, PROC8b, PROC15
	Environmental Release Categories: ERC1 Specific Environmental Release: none (usual on-site RMMs will be considered)
Processes, tasks, activities covered	Manufacture of substance. Includes, purification, associated laboratory activities, transfers, sampling, storage, large scale packing, maintenance, equipment cleaning and disposal of wastes.
Section 2	Operational conditions and risk management measures
Section 2.1	Control of worker exposure

Section 1	Exposure Scenario Title
Title	Manufacture of the substance (Industrial Application) CAS: 80-56-8
Product characteristics	
Physical form of product	Liquid, vapour pressure 0.5 - 10 kPa [OC4]. Liquid, vapour pressure > 10 kPa [OC5] for CS at temperature above 80°C.
Concentration of substance in product	Covers percentage substance in the product up to 100 % (unless stated differently) [G13].
Amounts used	No Limit
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2].
Other Operational Conditions affecting worker exposure	Assumes activities are at ambient temperature (unless stated differently) [G17].
Contributing Scenarios	Risk Management Measures
Number of contributing Scenario :	13
General process exposures (no sampling) General exposures (closed systems) [CS15]. (At temperature below 150°C.)	Handle substance within a closed system [E47]. Store substance within a closed system [E84].
Distillation with sample collection Continuous process [CS54]. With sample collection [CS56]. (At temperature below 60°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].
General production batch process reactor with sample collection Batch process [CS55]. With sample collection [CS56]. (At temperature below 50-55°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].
General production batch process reactor with sample collection Batch process [CS55]. With sample collection [CS56]. (At temperature below 80°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].

Section 1	Exposure Scenario Title
Title	Manufacture of the substance (Industrial Application) CAS: 80-56-8
General production holding/mixing tank Batch process [CS55]. With sample collection [CS56]. (At temperature below 80°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]). Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76]. Partial personal enclosure.
(Dis) Connecting flexible hoses (transfers) Bulk transfers [CS14].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]). Avoid carrying out activities involving exposure for more than 1 hour [OC27]. Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26].
Sampling from tankers or road tankers Product sampling [CS137].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]). Avoid carrying out activities involving exposure for more than 15 minutes [OC26]. Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26].
Drum/container filling Drum and small package filling [CS6]. Semi-bulk packaging [CS128].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]). Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76].
Equipment cleaning (nitrogen flow) Equipment cleaning and maintenance [CS39].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]). Drain down system prior to equipment break-in or maintenance [E65]. Limit the substance content in the product to 5% [OC17]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].
Waste management (STP): collection of condensates and other solids or liquids (or sludge) for off-site treatment and disposal or maintenance Disposal of wastes [CS28]. Equipment cleaning and maintenance [CS39].	Ensure operation is undertaken outdoors [E69]. Limit the substance content in the product to 1% [OC16]. Drain down system prior to equipment break-in or maintenance [E65]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].

Section 1	Exposure Scenario Title
Title	Manufacture of the substance (Industrial Application) CAS: 80-56-8
Waste management (STP): adsorption/desorption or condensation; anaerobic treatment of wastewater or sludge; Volatil Organic Compounds oxidation Disposal of wastes [CS28].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Limit the substance content in the product to 1% [OC16].
Waste management (STP): aerobic treatment (activated sludge, extensive aeration) Disposal of wastes [CS28].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Limit the substance content in the product to 1% [OC16].
QC laboratory work Laboratory activities [CS36].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Avoid carrying out activities involving exposure for more than 1 hour [OC27].
Section 2.2	Control of environmental exposure
Product characteristics	PrC1: Substance is a unique structure. PrC4b: Non hydrophobic PrC5: Readily biodegradable
Amounts used	A1: Fraction of EU tonnage used in region:1 A2: Regional use tonnage (tonnes/year): <16000t/year A3: Fraction of Regional tonnage used locally:1
Frequency and duration of use	FD2: Continuous release. FD4: Emissions days per year 365 days
Environmental factor no RMM	EF1: Local freshwater dilution factor:10 EF2: Local marine water dilution factor:100 EF3: Receiving surface water flow is 18000 m3/d.
Other Operational Conditions of use affecting environmental exposure	OOC2: Indoor use OOC4: Release fraction to air from process (initial release prior to RMM):ERC1=0.05 OOC5: Release fraction to wastewater from process (initial release prior to RMM):ERC1=0.06 OOC6: Release fraction to soil from process (initial release prior to RMM):ERC1=0.00001 OOC17: Process with efficient use of raw materials. OOC18: Volatile compounds subject to air emission controls. OOC25: Controlled application to agricultural soil.
Technical onsite conditions and measures to reduce or limit discharges, air emissions	TRC1b: Risk from environmental exposure is driven by freshwater sediment. TRC1d: Risk from environmental exposure is driven by marine sediment.

Section 1	Exposure Scenario Title				
Title	Manufacture of the substance (Industrial Application) CAS: 80-56-8				
and releases to soil	Applicable RMM for liquid, biodegradable substance RMMs taken into account for this scenario: combination of RMM 13.10, 13.21, 13.24 and 14.02 at default or maximum efficiency.				
	RMM number	RMM specific name	default / max RMM efficiency (%) for environmental compartment		
			air	water	soil
	E13.10	Chemical treatment – Precipitation	n.a.	unknown	n.a.
	E13.21	Biological treatment – Aerobic	n.a.	76/96	n.a.
	E13.24	Biological treatment - Sludge treatment e.g. thermal sludge reduction	n.a.	60/98	n.a.
	E14.02	Disposal - Hazardous Waste Incineration	n.a.	high	99
	Refined release fractions for manufacture		0.05	0.000075	0.00000
Organisation measures to prevent/limit release from site	OMS4: Prevent environmental discharge consistent with regulatory requirements.				
Conditions and measures related to municipal sewage treatment plant	In case of release in marine waters, municipal STP is not assumed but specific STP For no marine release, industrial or domestic STP is assumed. STP7b: Risk from environmental exposure is driven by freshwater sediment. STP7d: Risk from environmental exposure is driven by marine sediment.				
Conditions and measures related to external treatment of waste for disposal	ETW3: External treatment and disposal of waste should comply with applicable local and/or national regulations.				
Conditions and measures related to external recovery of waste	ERW1: External recovery and recycling of waste should comply with applicable local and/or national regulations.				
Other environmental control measures additional to above	None				
Section 3	Exposure Estimation				
Section 3.1 - Health	The ECETOC TRA tool has been used to estimate Tier 1 workplace exposures unless otherwise indicated [G21]. The ART model has been used to estimate Tier 2 workplace exposures.				
Section 3.2 - Environment	The ECETOC TRA tool has been used to estimate the risk for man via the environment.				
Section 4	Guidance to check compliance with the Exposure Scenario				

Section 1	Exposure Scenario Title
Title	Manufacture of the substance (Industrial Application) CAS: 80-56-8
Section 4.1 - Health	Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented [G22]. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels [G23].
Section 4.2 - Environment	Risk assessment for man via the environment : DSU8: If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required

9.1.2 Exposure Estimation: Manufacture of the substance (Industrial Application)

9.1.2.1 Human Health

Exposure Estimation Worker - Manufacture of the substance (Industrial Application)

Generic Exposure Scenario		Contributing Scenarios			Manufacture of the substance: worker exposure		
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory systemic Exposure - (ppm from ECETOC-TRA results and mg/m3 from ART-model results)	Predicted Dermal Local Exposure (mg/cm ²) - modified
Manufacture of the substance (Industrial Application)	Industrial - SU3	General process exposures (no sampling)	General exposures (closed systems) [CS15].	1	ECETOC - TRA	7,00E-03	2,80E-02
Manufacture of the substance (Industrial Application)	Industrial - SU3	Distillation with sample collection	Continuous process [CS54]. With sample collection [CS56].	2	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	1,12E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	General production batch process reactor with sample collection	Batch process [CS55]. With sample collection [CS56].	3	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	2,80E-02

Generic Exposure Scenario		Contributing Scenarios			Manufacture of the substance: worker exposure		
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory systemic Exposure - (ppm from ECETOC-TRA results and mg/m3 from ART-model results)	Predicted Dermal Local Exposure (mg/cm ²) - modified
Manufacture of the substance (Industrial Application)	Industrial - SU3	General production batch process reactor with sample collection	Batch process [CS55]. With sample collection [CS56].	3	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	3,20E+00	2,80E-02
Manufacture of the substance (Industrial Application)	Industrial - SU3	General production holding/mixing tank	Batch process [CS55]. With sample collection [CS56].	4	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,90E+00	1,12E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	(Dis) Connecting flexible hoses (transfers)	Bulk transfers [CS14].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	2,80E+00	1,12E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	Sampling from tankers or road tankers	Product sampling [CS137].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	7,00E-01	1,12E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	Drum/container filling	Drum and small package filling [CS6]. Semi-bulk packaging [CS128].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	5,30E+00	1,12E-01

Generic Exposure Scenario		Contributing Scenarios			Manufacture of the substance: worker exposure		
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory systemic Exposure - (ppm from ECETOC-TRA results and mg/m3 from ART-model results)	Predicted Dermal Local Exposure (mg/cm ²) - modified
Manufacture of the substance (Industrial Application)	Industrial - SU3	Equipment cleaning (nitrogen flow)	Equipment cleaning and maintenance [CS39].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	7,00E-01	1,12E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	Waste management (STP): collection of condensates and other solids or liquids (or sludge) for off-site treatment and disposal or maintenance	Disposal of wastes [CS28]. Equipment cleaning and maintenance [CS39].	8b	ECETOC - TRA	3,50E-01	5,60E-02
Manufacture of the substance (Industrial Application)	Industrial - SU3	Waste management (STP): adsorption/desorption or condensation; anaerobic treatment of wastewater or sludge; Volatil Organic Compounds oxidation	Disposal of wastes [CS28].	3	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	2,80E-03
Manufacture of the substance (Industrial Application)	Industrial - SU3	Waste management (STP): aerobic treatment (activated sludge, extensive aeration)	Disposal of wastes [CS28].	4	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	5,60E-02
Manufacture of the substance (Industrial Application)	Industrial - SU3	QC laboratory work	Laboratory activities [CS36].	15	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	2,80E+00	2,80E-02

See Appendix 1.a.1, Appendix 2.a.1, Appendix 1.b.1, Appendix 2.b.1 and Appendix 4

9.1.2.2 Environment

The substance does not meet the criteria for classification as dangerous for the environment but is manufactured/ imported at more than 1000 t/y. Therefore only the risk for man via the environment was assessed. The substance is not classified as toxic (no R48 phrase), not classified as a carcinogen nor mutagen, not toxic to reproduction (category 1 or 2). Secondary poisoning was considered as not relevant as the substance is not PBT and has no potential to cause toxic effects if accumulated in higher organisms, based on classification data. Input parameters for regional exposure estimation and regional concentrations are provided in paragraph 9.12.

Risk Characterisation (extract from CSR)

10. RISK CHARACTERISATION

10.1 Manufacture of the substance (Industrial Application)

10.1.1 Human Health – Workers

Due to the toxicological profile of Alpha-Pinene, no systemic effects are expected after dermal exposure. However, this substance is skin sensitising and a dermal DNEL for local effects was derived to evaluate the remaining risks after RMMs and OCs are implemented. The minimum RMM to protect against skin sensitising properties of substances is gloves (which will be considered for all PROCs).

Apart from those local effects, systemic effects were considered and an inhalation DNEL for systemic long-term effects was calculated for workers.

Local and systemic effects being different toxicological end-points, the risk characterisation ratios calculated for each kind of effect will be considered apart (not added) to decide if the risk is acceptable or not.

Risk characterisation - Worker - Manufacture of the substance (Industrial Application)

Generic Exposure Scenario		Contributing Scenarios			Risk Characterization	
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	RCR (inhalation systemic)	RCR (dermal local)
Manufacture of the substance (Industrial Application)	Industrial - SU3	General process exposures (no sampling)	General exposures (closed systems) [CS15].	1	6,63E-03	1,74E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	Distillation with sample collection	Continuous process [CS54]. With sample collection [CS56].	2	7,02E-01	6,95E-01

Generic Exposure Scenario		Contributing Scenarios			Risk Characterization	
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	RCR (inhalation systemic)	RCR (dermal local)
Manufacture of the substance (Industrial Application)	Industrial - SU3	General production batch process reactor with sample collection	Batch process [CS55]. With sample collection [CS56].	3	7,02E-01	1,74E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	General production batch process reactor with sample collection	Batch process [CS55]. With sample collection [CS56].	3	5,35E-01	1,74E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	General production holding/mixing tank	Batch process [CS55]. With sample collection [CS56].	4	8,19E-01	6,95E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	(Dis) Connecting flexible hoses (transfers)	Bulk transfers [CS14].	8b	4,68E-01	6,95E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	Sampling from tankers or road tankers	Product sampling [CS137].	8b	1,17E-01	6,95E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	Drum/container filling	Drum and small package filling [CS6]. Semi-bulk packaging [CS128].	8b	8,86E-01	6,95E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	Equipment cleaning (nitrogen flow)	Equipment cleaning and maintenance [CS39].	8b	6,63E-01	6,95E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	Waste management (STP): collection of condensates and other solids or liquids (or sludge) for off-site treatment and disposal or maintenance	Disposal of wastes [CS28]. Equipment cleaning and maintenance [CS39].	8b	3,32E-01	3,48E-01
Manufacture of the substance (Industrial Application)	Industrial - SU3	Waste management (STP): adsorption/desorption or condensation; anaerobic treatment of wastewater or sludge; Volatil Organic Compounds oxidation	Disposal of wastes [CS28].	3	7,02E-01	1,74E-02
Manufacture of the substance (Industrial Application)	Industrial - SU3	Waste management (STP): aerobic treatment (activated sludge, extensive aeration)	Disposal of wastes [CS28].	4	7,02E-01	3,48E-01

Generic Exposure Scenario		Contributing Scenarios			Risk Characterization	
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	RCR (inhalation systemic)	RCR (dermal local)
Manufacture of the substance (Industrial Application)	Industrial - SU3	QC laboratory work	Laboratory activities [CS36].	15	4,68E-01	1,74E-01

See Appendix 3.a.1 and Appendix 3.b.1

10.1.2 Environment

The substance does not meet the criteria for classification as dangerous for the environment but is manufactured/ imported at more than 1000 t/y. Therefore only the risk for man via the environment was assessed. The substance is not classified as toxic (no R48 phrase), not classified as a carcinogen nor mutagen, not toxic to reproduction (category 1 or 2). Secondary poisoning was considered as not relevant as the substance is not PBT and has no potential to cause toxic effects if accumulated in higher organisms, based on classification data. Risk characterization ratio for man via the environment is provided in paragraph 10.12.

ES 2. Users by workers in industrial settings: Exposure Scenario for the use of the substance as an intermediate. (Referred to as Exposure scenario No. 2 in CSR)

Process category (PROC):

- PROC 1: Use in closed process, no likelihood of exposure
- PROC 2: Use in closed, continuous process with occasional controlled exposure
- PROC 3: Use in closed batch process (synthesis or formulation)
- PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises
- PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
- PROC 15: Use as laboratory reagent

Environmental release category (ERC):

- ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates)

Sector of end use (SU):

- SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)
- SU 9: Manufacture of fine chemicals

Subsequent service life relevant for that use?: no

Exposure Assessment (extracted from Chemical Safety Report)

9.2 Substance used as Intermediate (transformed into another substance)

9.2.1 Exposure Scenario : Substance used as Intermediate (transformed into another substance)

Section 1	Exposure Scenario Title
Title	Substance used as Intermediate (transformed into another substance) CAS: 80-56-8
Use Descriptor	Sector of Use: SU 3 Industrial Uses. SU 8 Manufacture of bulk, large scale chemicals (including petroleum products). SU 9 Manufacture of fine chemicals.
	Process Categories: PROC1, PROC2, PROC3, PROC4, PROC8b, PROC15
	Environmental Release Categories: ERC6a Specific Environmental Release: none (usual on-site RMMs will be considered)
Processes, tasks, activities covered	Chemical synthesis or distillation. Includes associated laboratory activities, transfers, sampling, storage, maintenance, equipment cleaning and disposal of wastes.
Section 2	Operational conditions and risk management measures

Section 1	Exposure Scenario Title
Title	Substance used as Intermediate (transformed into another substance) CAS: 80-56-8
Section 2.1	Control of worker exposure
Product characteristics	
Physical form of product	Liquid, vapour pressure 0.5 - 10 kPa [OC4]. Liquid, vapour pressure > 10 kPa [OC5] for CS at temperature above 80°C.
Concentration of substance in product	Covers percentage substance in the product up to 100 % (unless stated differently) [G13].
Amounts used	No Limit
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2].
Other Operational Conditions affecting worker exposure	Assumes activities are at ambient temperature (unless stated differently) [G17].
Contributing Scenarios	Risk Management Measures
Number of contributing Scenario :	13
General process exposures (no sampling) General exposures (closed systems) [CS15]. (At temperature below 150°C.)	Handle substance within a closed system [E47]. Store substance within a closed system [E84].
Distillation with sample collection Continuous process [CS54]. With sample collection [CS56]. (At temperature below 50-60°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].
General production batch process reactor with sample collection Batch process [CS55]. With sample collection [CS56]. (At temperature	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].

Section 1	Exposure Scenario Title
Title	Substance used as Intermediate (transformed into another substance) CAS: 80-56-8
below 50-55°C.)	
General production batch process reactor with sample collection Batch process [CS55]. With sample collection [CS56]. (At temperature below 80°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].
General production holding/mixing tank Batch process [CS55]. With sample collection [CS56]. (At temperature below 80°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76]. Partial personal enclosure.
(Dis) Connecting flexible hoses (transfers) Bulk transfers [CS14].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [Chemically resistant gloves (Gloves with available permeation data indicating that the material of construction offers good protection for the substance) with basic employee training. Use suitable eye protection [PPE26].
Sampling from tankers or road tankers Product sampling [CS137].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [Chemically resistant gloves (Gloves with available permeation data indicating that the material of construction offers good protection for the substance) with basic employee training. Use suitable eye protection [PPE26].
Equipment cleaning (nitrogen flow) Equipment cleaning and maintenance[CS39].	Drain down system prior to equipment break-in or maintenance [E65]. Limit the substance content in the product to 5% [OC17]. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26]. Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26].

Section 1	Exposure Scenario Title
Title	Substance used as Intermediate (transformed into another substance) CAS: 80-56-8
Waste management (STP): collection of condensates and other solids or liquids (or sludge) for off-site treatment and disposal or maintenance Disposal of wastes [CS28]. Equipment cleaning and maintenance [CS39].	Ensure operation is undertaken outdoors [E69]. Limit the substance content in the product to 1% [OC16]. Drain down system prior to equipment break-in or maintenance [E65]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].
Waste management (STP): adsorption/desorption or condensation; anaerobic treatment of wastewater or sludge; Volatil Organic Compounds oxidation Disposal of wastes [CS28].	Limit the substance content in the product to 1% [OC16]. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]).
Waste management (STP): aerobic treatment (activated sludge, extensive aeration) Disposal of wastes [CS28].	Limit the substance content in the product to 1% [OC16]. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]).
QC laboratory work Laboratory activities [CS36].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]). Avoid carrying out activities involving exposure for more than 1 hour [OC27].
Reception of goods / Discharging of vessels, pumping, with sample collection. Storage / Filling of containers Transfer from/pouring from containers [CS22].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]). Avoid carrying out activities involving exposure for more than 1 hour [OC27]. Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76].

Section 1	Exposure Scenario Title			
Title	Substance used as Intermediate (transformed into another substance) CAS: 80-56-8			
With sample collection [CS56]. Non-dedicated facility [CS82].				
Section 2.2	Control of environmental exposure			
Product characteristics	PrC1: Substance is a unique structure. PrC4b: Non hydrophobic PrC5: Readily biodegradable			
Amounts used	A1: Fraction of EU tonnage used in region:1 A2: Regional use tonnage (tonnes/year): <12000t/year A3: Fraction of Regional tonnage used locally:1			
Frequency and duration of use	FD2: Continuous release. FD4: Emissions days per year 365 days			
Environmental factor no RMM	EF1: Local freshwater dilution factor:10 EF2: Local marine water dilution factor:100 EF3: Receiving surface water flow is 18000 m3/d.			
Other Operational Conditions of use affecting environmental exposure	OOC2: Indoor use OOC4: Release fraction to air from process (initial release prior to RMM): ERC6a=0.05 OOC5: Release fraction to wastewater from process (initial release prior to RMM): ERC6a=0.02 OOC6: Release fraction to soil from process (initial release prior to RMM): ERC6a=0.001 OOC17: Process with efficient use of raw materials. OOC18: Volatile compounds subject to air emission controls. OOC25: Controlled application to agricultural soil.			
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	TRC1b: Risk from environmental exposure is driven by freshwater sediment. TRC1d: Risk from environmental exposure is driven by marine sediment. Applicable RMM for liquid, biodegradable substance RMMs taken into account for this scenario: combination of RMM 13.10, 13.21, 13.24 and 14.02 at default or maximum efficiency.			
	RMM number	RMM specific name	default / max RMM efficiency (%) environmental compartment	
			air	water
	E13.10	Chemical treatment – Precipitation	n.a.	unknown
	E13.21	Biological treatment – Aerobic	n.a.	76/96
	E13.24	Biological treatment - Sludge treatment e.g. thermal sludge reduction	n.a.	60/98
	E14.02	Disposal - Hazardous Waste Incineration	n.a.	high
				soil
				n.a
				n.a
				n.a
				99

Section 1	Exposure Scenario Title			
Title	Substance used as Intermediate (transformed into another substance) CAS: 80-56-8			
	Refined release fractions for use as intermediate	0.05	0.0005	0.001
Organisation measures to prevent/limit release from site	OMS4: Prevent environmental discharge consistent with regulatory requirements.			
Conditions and measures related to municipal sewage treatment plant	In case of release in marine waters, municipal STP is not assumed but specific STP For no marine release, industrial or domestic STP is assumed. STP7b: Risk from environmental exposure is driven by freshwater sediment. STP7d: Risk from environmental exposure is driven by marine sediment.			
Conditions and measures related to external treatment of waste for disposal	ETW3: External treatment and disposal of waste should comply with applicable local and/or national regulations.			
Conditions and measures related to external recovery of waste	ERW1: External recovery and recycling of waste should comply with applicable local and/or national regulations.			
Other environmental control measures additional to above	None			
Section 3.1 - Health	Exposure Estimation			
The ECETOC TRA tool has been used to estimate Tier 1 workplace exposures unless otherwise indicated [G21]. The ART model has been used to estimate Tier 2 workplace exposures.				
Section 3	Exposure Estimation			
Section 3.1 - Health	The ECETOC TRA tool has been used to estimate Tier 1 workplace exposures unless otherwise indicated [G21]. The ART model has been used to estimate Tier 2 workplace exposures.			
Section 3.2 - Environment	The ECETOC TRA tool has been used to estimate the risk for man via the environment.			
Section 4	Guidance to check compliance with the Exposure Scenario			
Section 4.1 - Health	Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented [G22]. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels [G23].			
Section 4.2 - Environment	Risk assessment for man via the environment : DSU8: If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required			

9.2.2 Exposure Estimation: Substance used as Intermediate (transformed into another substance)

9.2.2.1 Human Health

Exposure Estimation Worker - Substance used as Intermediate (transformed into another substance)
(Industrial Application)

Generic Exposure Scenario		Contributing Scenarios			Substance used as Intermediate (transformed into another substance): worker exposure		
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory Exposure - (ppm from ECETOC-TRA results and mg/m3 from ART-model results)	Predicted Dermal Local Exposure (mg/cm ²) - modified
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	General process exposures (no sampling)	General exposures (closed systems) [CS15].	1	ECETOC - TRA	7,00E-03	2,80E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Distillation with sample collection	Continuous process [CS54]. With sample collection [CS56].	2	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	1,12E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	General production batch process reactor with sample collection	Batch process [CS55]. With sample collection [CS56].	3	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	2,80E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	General production batch process reactor with sample collection	Batch process [CS55]. With sample collection [CS56].	3	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	3,20E+00	2,80E-02

Generic Exposure Scenario		Contributing Scenarios			Substance used as Intermediate (transformed into another substance): worker exposure		
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory Exposure - (ppm from ECETOC-TRA results and mg/m3 from ART-model results)	Predicted Dermal Local Exposure (mg/cm ²) - modified
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	General production holding/mixing tank	Batch process [CS55]. With sample collection [CS56].	4	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,90E+00	5,60E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	(Dis) Connecting flexible hoses (transfers)	Bulk transfers [CS14].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	2,80E+00	1,10E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Sampling from tankers or road tankers	Product sampling [CS137].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	7,00E-01	1,10E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Equipment cleaning (nitrogen flow)	Equipment cleaning and maintenance [CS39].	8b	ECETOC - TRA	7,00E-01	1,10E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Waste management (STP): collection of condensates and other solids or liquids (or sludge) for off-site treatment and disposal or maintenance	Disposal of wastes [CS28]. Equipment cleaning and maintenance [CS39].	8b	ECETOC - TRA	3,50E-01	5,60E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Waste management (STP): adsorption/desorption or condensation; anaerobic treatment of wastewater or sludge; Volatil Organic Compounds oxidation	Disposal of wastes [CS28].	3	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	2,80E-03

Generic Exposure Scenario		Contributing Scenarios			Substance used as Intermediate (transformed into another substance): worker exposure		
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory Exposure - (ppm from ECETOC-TRA results and mg/m3 from ART-model results)	Predicted Dermal Local Exposure (mg/cm ²) - modified
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Waste management (STP): aerobic treatment (activated sludge, extensive aeration)	Disposal of wastes [CS28].	4	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	5,60E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	QC laboratory work	Laboratory activities [CS36].	15	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	2,80E+00	2,80E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Reception of goods / Discharging of vessels, pumping, with sample collection. Storage / Filling of containers	Transfer from/pouring from containers [CS22]. With sample collection [CS56]. Non-dedicated facility [CS82].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	1,60E+00	1,12E-01

See Appendix 1.a.2, Appendix 2.a.2, Appendix 1.b.2 and Appendix 2.b.2 and Appendix 4

9.2.2.2 Environment

The substance does not meet the criteria for classification as dangerous for the environment but is manufactured/ imported at more than 1000 t/y. Therefore only the risk for man via the environment was assessed. The substance is not classified as toxic (no R48 phrase), not classified as a carcinogen nor mutagen, not toxic to reproduction (category 1 or 2). Secondary poisoning was considered as not relevant as the substance is not PBT and has no potential to cause toxic effects if accumulated in higher organisms, based on classification data. Input parameters for regional exposure estimation and regional concentrations are provided in paragraph 9.12.

Risk Characterisation (extracted from Chemical Safety Report)

10.2 Substance used as Intermediate (transformed into another substance)

10.2.1 Human Health – Workers

Due to the toxicological profile of Alpha-Pinene, no systemic effects are expected after dermal exposure. However, this substance is skin sensitising and a dermal DNEL for local effects was derived to evaluate the remaining risks after RMMs and OCs are implemented. The minimum RMM to protect against skin sensitising properties of substances is gloves (which will be considered for all PROCs).

Apart from those local effects, systemic effects were considered and an inhalation DNEL for systemic long-term effects was calculated for workers.

Local and systemic effects being different toxicological end-points, the risk characterisation ratios calculated for each kind of effect will be considered apart (not added) to decide if the risk is acceptable or not.

Risk characterisation - Worker - Substance used as Intermediate (transformed into another substance)

Generic Exposure Scenario		Contributing Scenarios			Risk Characterization	
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	RCR (inhalation systemic)	RCR (dermal local)
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	General process exposures (no sampling)	General exposures (closed systems) [CS15].	1	6,63E-03	2,41E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Distillation with sample collection	Continuous process [CS54]. With sample collection [CS56].	2	7,02E-01	9,64E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	General production batch process reactor with sample collection	Batch process [CS55]. With sample collection [CS56].	3	7,02E-01	2,41E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	General production batch process reactor with sample collection	Batch process [CS55]. With sample collection [CS56].	3	5,35E-01	2,41E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	General production holding/mixing tank	Batch process [CS55]. With sample collection [CS56].	4	8,19E-01	4,82E-01

Generic Exposure Scenario		Contributing Scenarios			Risk Characterization	
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	RCR (inhalation systemic)	RCR (dermal local)
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	(Dis) Connecting flexible hoses (transfers)	Bulk transfers [CS14].	8b	4,68E-01	6,95E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Sampling from tankers or road tankers	Product sampling [CS137].	8b	7,00E-01	6,95E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Equipment cleaning (nitrogen flow)	Equipment cleaning and maintenance [CS39].	8b	6,63E-01	6,95E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Waste management (STP): collection of condensates and other solids or liquids (or sludge) for off-site treatment and disposal or maintenance	Disposal of wastes [CS28]. Equipment cleaning and maintenance [CS39].	8b	3,32E-01	3,48E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Waste management (STP): adsorption/desorption or condensation; anaerobic treatment of wastewater or sludge; Volatil Organic Compounds oxidation	Disposal of wastes [CS28].	3	7,02E-01	1,74E-02
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Waste management (STP): aerobic treatment (activated sludge, extensive aeration)	Disposal of wastes [CS28].	4	7,02E-01	3,48E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	QC laboratory work	Laboratory activities [CS36].	15	4,68E-01	1,74E-01
Substance used as Intermediate (transformed into another substance)	Industrial - SU3	Reception of goods / Discharging of vessels, pumping, with sample collection. Storage / Filling of containers	Transfer from/pouring from containers [CS22]. With sample collection [CS56]. Non-dedicated facility [CS82].	8b	2,68E-01	6,95E-01

See Appendix 3.a.2, Appendix 3.b.2 and Appendix 4

10.2.2 Environment

The substance does not meet the criteria for classification as dangerous for the environment but is manufactured/ imported at more than 1000 t/y. Therefore only the risk for man via the environment was assessed. The substance is not classified as toxic (no R48 phrase), not classified as a carcinogen nor mutagen, not toxic to reproduction (category 1 or 2). Secondary poisoning was considered as not relevant as the substance is not PBT and has no potential to cause toxic effects if accumulated in higher organisms, based on classification data. Risk characterization ratio for man via the environment is provided in paragraph 10.12.

ES 3. Users by workers in industrial settings: Exposure Scenario for the use of the substance as a monomer for polymerization. (Referred to as Exposure scenario No. 3 in CSR)

Process category (PROC):

- PROC 1: Use in closed process, no likelihood of exposure
- PROC 2: Use in closed, continuous process with occasional controlled exposure
- PROC 3: Use in closed batch process (synthesis or formulation)
- PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises
- PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
- PROC 15: Use as laboratory reagent

Environmental release category (ERC):

- ERC 6c: Industrial use of monomers for manufacture of thermoplastics

Sector of end use (SU):

- SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)
- SU 9: Manufacture of fine chemicals

Subsequent service life relevant for that use?: no

Exposure Assessment. (extract from the Chemical Safety Report)

9.3 Substance use as Monomer for Polymerisation (Industrial Application)

9.3.1 Exposure Scenario : Substance use as Monomer for Polymerisation (Industrial Application)

Section 1	Exposure Scenario Title
Title	Substance use as Monomer for Polymerisation (Industrial Application) CAS: 80-56-8
Use Descriptor	Sector of Use: SU 3 Industrial Uses. SU 8 Manufacture of bulk, large scale chemicals (including petroleum products). SU 9 Manufacture of fine chemicals.
	Process Categories: PROC1, PROC2, PROC3, PROC4, PROC8b, PROC15
	Environmental Release Categories: ERC6c Specific Environmental Release: none (usual on-site RMMs will be considered)
Processes, tasks,	Polymerisation. Includes associated laboratory activities, transfers,

Section 1	Exposure Scenario Title
Title	Substance use as Monomer for Polymerisation (Industrial Application) CAS: 80-56-8
activities covered	sampling, storage, maintenance and equipment cleaning and disposal of wastes.
Section 2	Operational conditions and risk management measures
Section 2.1	Control of worker exposure
Product characteristics	
Physical form of product	Liquid, vapour pressure 0.5 - 10 kPa [OC4]. Liquid, vapour pressure > 10 kPa [OC5] for CS at temperature above 80°C.
Concentration of substance in product	Covers percentage substance in the product up to 100 % (unless stated differently) [G13].
Amounts used	No Limit
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2].
Other Operational Conditions affecting worker exposure	Assumes activities are at ambient temperature (unless stated differently) [G17].
Contributing Scenarios	Risk Management Measures
Number of contributing Scenario :	12
Polymerisation in closed, continuous process. (At temperature below 85°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76].
Polymerisation in closed, continuous process. (At temperature below 40°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76].
Polymerisation. (Use in batch and other process (synthesis) where opportunity for exposure arises) (At temperature below 40°C.)	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76].
General process exposures (no sampling) General exposures (closed systems) [CS15].	Handle substance within a closed system [E47]. Store substance within a closed system [E84].

Section 1	Exposure Scenario Title
Title	Substance use as Monomer for Polymerisation (Industrial Application) CAS: 80-56-8
(Dis) Connecting flexible hoses (transfers) Bulk transfers [CS14].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Avoid carrying out activities involving exposure for more than 1 hour [OC27]. Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26].
Sampling from tankers or road tankers Product sampling [CS137].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26]. Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26].
Equipment cleaning Equipment cleaning and maintenance [CS39].	Drain down system prior to equipment break-in or maintenance [E65]. Limit the substance content in the product to 5% [OC17]. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].
Waste management (STP): collection of condensates and other solids or liquids (or sludge) for off-site treatment and disposal or maintenance Disposal of wastes [CS28]. Equipment cleaning and maintenance [CS39].	Ensure operation is undertaken outdoors [E69]. Limit the substance content in the product to 1% [OC16]. Drain down system prior to equipment break-in or maintenance [E65]. Avoid carrying out activities involving exposure for more than 15 minutes [OC26].
Waste management (STP): adsorption/desorption or condensation; anaerobic treatment of wastewater or sludge; Volatil Organic Compounds oxidation Disposal of wastes [CS28].	Limit the substance content in the product to 1% [OC16]. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11].
Waste management (STP): aerobic treatment (activated sludge, extensive aeration) Disposal of wastes [CS28].	Limit the substance content in the product to 1% [OC16]. Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11].
QC laboratory work	Provide a good standard of general ventilation (not less than 3 to 5 air

Section 1	Exposure Scenario Title
Title	Substance use as Monomer for Polymerisation (Industrial Application) CAS: 80-56-8
Laboratory activities [CS36].	changes per hour [E11]. Avoid carrying out activities involving exposure for more than 1 hour [OC27].
Reception of goods / Discharging of vessels, pumping, with sample collection. Storage / Filling of containers Transfer from/pouring from containers [CS22]. With sample collection [CS56]. Non-dedicated facility [CS82].	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour [E11]. Avoid carrying out activities involving exposure for more than 1 hour [OC27]. Gloves with available permeation data indicating that the material of construction offers good protection for the substance. Use suitable eye protection [PPE26]. Ensure material transfers are under containment or extract ventilation [E66]. Ensure samples are obtained under containment or extract ventilation [E76].
Section 2.2	Control of environmental exposure
Product characteristics	PrC1: Substance is a unique structure. PrC4b: Non hydrophobic PrC5: Readily biodegradable
Amounts used	A1: Fraction of EU tonnage used in region:1 A2: Regional use tonnage (tonnes/year): <5500t/year A3: Fraction of Regional tonnage used locally:1
Frequency and duration of use	FD2: Continuous release. FD4: Emissions days per year 365 days
Environmental factor no RMM	EF1: Local freshwater dilution factor:10 EF2: Local marine water dilution factor:100 EF3: Receiving surface water flow is 18000 m3/d.
Other Operational Conditions of use affecting environmental exposure	OOC2: Indoor use OOC4: Release fraction to air from process (initial release prior to RMM): ERC6c=0.05 OOC5: Release fraction to wastewater from process (initial release prior to RMM): ERC6c=0.05 OOC6: Release fraction to soil from process (initial release prior to RMM): ERC6c=0.00 OOC17: Process with efficient use of raw materials. OOC18: Volatile compounds subject to air emission controls. OOC25: Controlled application to agricultural soil.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	TRC1b: Risk from environmental exposure is driven by freshwater sediment. TRC1d: Risk from environmental exposure is driven by marine sediment. Applicable RMM for liquid, biodegradable substance RMMs taken into account for this scenario: combination of RMM 13.10, 13.21, 13.24 and 14.02 at default or maximum efficiency.

Section 1	Exposure Scenario Title				
Title	Substance use as Monomer for Polymerisation (Industrial Application) CAS: 80-56-8				
	RMM number	RMM specific name	default / max RMM efficiency (%) for environmental compartment		
			air	water	soil
	E13.10	Chemical treatment – Precipitation	n.a.	unknown	n.a.
	E13.21	Biological treatment – Aerobic	n.a.	76/96	n.a.
	E13.24	Biological treatment - Sludge treatment e.g. thermal sludge reduction	n.a.	60/98	n.a.
	E14.02	Disposal - Hazardous Waste Incineration	n.a.	high	99
	Refined release fractions for use as monomer for polymerisation		0.05	0.00008	0.00
Organisation measures to prevent/limit release from site	OMS4: Prevent environmental discharge consistent with regulatory requirements.				
Conditions and measures related to municipal sewage treatment plant	In case of release in marine waters, municipal STP is not assumed but specific STP For no marine release, industrial or domestic STP is assumed. STP7b: Risk from environmental exposure is driven by freshwater sediment. STP7d: Risk from environmental exposure is driven by marine sediment.				
Conditions and measures related to external treatment of waste for disposal	ETW3: External treatment and disposal of waste should comply with applicable local and/or national regulations.				
Conditions and measures related to external recovery of waste	ERW1: External recovery and recycling of waste should comply with applicable local and/or national regulations.				
Other environmental control measures additional to above	None				
Section 3	Exposure Estimation				
Section 3.1 - Health	The ECETOC TRA tool has been used to estimate Tier 1 workplace exposures unless otherwise indicated [G21]. The ART model has been used to estimate Tier 2 workplace exposures.				
Section 3.2 - Environment	The ECETOC TRA tool has been used to estimate the risk for man via the environment.				
Section 4	Guidance to check compliance with the Exposure Scenario				
Section 4.1 - Health	Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented				

Section 1	Exposure Scenario Title
Title	Substance use as Monomer for Polymerisation (Industrial Application) CAS: 80-56-8
	[G22]. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels [G23].
Section 4.2 - Environment	Risk assessment for man via the environment : DSU8: If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required

9.3.2 Exposure Estimation: Substance use as Monomer for Polymerisation (Industrial Application)

9.3.2.1 Human Health

Exposure Estimation - Worker - Substance use as Monomer for Polymerisation (Industrial Application)

Generic Exposure Scenario		Contributing Scenarios			Substance use as Monomer for Polymerisation: worker exposure		
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory Exposure - (ppm from ECETOC-TRA results and mg/m3 from ART-model results)	Predicted Dermal Local Exposure (mg/cm ²) - modified
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Polymerisation in closed, continuous process	-	2	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	5,30E+00	1,10E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Polymerisation in closed, batch process	-	3	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	3,90E+00	3,00E-02
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Polymerisation	-	4	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	5,30E+00	1,10E-01

Generic Exposure Scenario		Contributing Scenarios			Substance use as Monomer for Polymerisation: worker exposure		
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory Exposure - (ppm from ECETOC-TRA results and mg/m3 from ART-model results)	Predicted Dermal Local Exposure (mg/cm ²) - modified
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	General process exposures (no sampling)	General exposures (closed systems) [CS15].	1	ECETOC - TRA	7,00E-03	2,80E-02
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	(Dis) Connecting flexible hoses (transfers)	Bulk transfers [CS14].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	2,80E+00	1,12E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Sampling from tankers or road tankers	Product sampling [CS137].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	7,00E-01	1,12E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Equipment cleaning	Equipment cleaning and maintenance [CS39].	8b	ECETOC - TRA	7,00E-01	1,12E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Waste management (STP): collection of condensates and other solids or liquids (or sludge) for off-site treatment and disposal or maintenance	Disposal of wastes [CS28]. Equipment cleaning and maintenance [CS39].	8b	ECETOC - TRA	3,50E-01	5,60E-02
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Waste management (STP): adsorption/desorption or condensation; anaerobic treatment of wastewater or sludge; Volatil Organic Compounds oxidation	Disposal of wastes [CS28].	3	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	2,80E-03

Generic Exposure Scenario		Contributing Scenarios			Substance use as Monomer for Polymerisation: worker exposure		
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory Exposure - (ppm from ECETOC-TRA results and mg/m3 from ART-model results)	Predicted Dermal Local Exposure (mg/cm ²) - modified
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Waste management (STP): aerobic treatment (activated sludge, extensive aeration)	Disposal of wastes [CS28].	4	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	4,20E+00	5,60E-02
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	QC laboratory work	Laboratory activities [CS36].	15	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	2,80E+00	2,80E-02
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Reception of goods / Discharging of vessels, pumping, with sample collection. Storage / Filling of containers	Transfer from/pouring from containers [CS22]. With sample collection [CS56]. Non-dedicated facility [CS82].	8b	ECETOC - TRA for Dermal exposure and ART model for Inhalatory exposure	1,60E+00	1,12E-01

See Appendix 1.a.3, Appendix 2.a.3, Appendix 1.b.3, Appendix 2.b.3 and Appendix 4

9.3.2.2 Environment

The substance does not meet the criteria for classification as dangerous for the environment but is manufactured/ imported at more than 1000 t/y. Therefore only the risk for man via the environment was assessed. The substance is not classified as toxic (no R48 phrase), not classified as a carcinogen nor mutagen, not toxic to reproduction (category 1 or 2). Secondary poisoning was considered as not relevant as the substance is not PBT and has no potential to cause toxic effects if accumulated in higher organisms, based on classification data. Input parameters for regional exposure estimation and regional concentrations are provided in paragraph 9.12.

Risk Characterisation (extract from the Chemical Safety Report)

10.3 Substance use as Monomer for Polymerisation (Industrial Application)

10.3.1 Human Health – Workers

Due to the toxicological profile of Alpha-Pinene, no systemic effects are expected after dermal exposure. However, this substance is skin sensitising and a dermal DNEL for local effects was derived to evaluate the remaining risks after RMMs and OCs are implemented. The minimum RMM to protect against skin sensitising properties of substances is gloves (which will be considered for all PROCs).

Apart from those local effects, systemic effects were considered and an inhalation DNEL for systemic long-term effects was calculated for workers.

Local and systemic effects being different toxicological end-points, the risk characterisation ratios calculated for each kind of effect will be considered apart (not added) to decide if the risk is acceptable or not.

Risk characterisation - Worker - Substance use as Monomer for Polymerisation (Industrial Application)

Generic Exposure Scenario		Contributing Scenarios			Risk Characterization	
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	RCR (inhalation systemic)	RCR (dermal local)
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Polymerisation in closed, continuous process	-	2	8,86E-01	6,95E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Polymerisation in closed, batch process	-	3	6,52E-01	1,74E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Polymerisation	-	4	8,86E-01	6,95E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	General process exposures (no sampling)	General exposures (closed systems) [CS15].	1	6,63E-03	1,74E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	(Dis) Connecting flexible hoses (transfers)	Bulk transfers [CS14].	8b	4,68E-01	6,95E-01

Generic Exposure Scenario		Contributing Scenarios			Risk Characterization	
Short Title	Life Cycle Stage / Area of Application	Title	Supporting phrase	Process Category (PROC)	RCR (inhalation systemic)	RCR (dermal local)
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Sampling from tankers or road tankers	Product sampling [CS137].	8b	1,17E-01	6,95E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Equipment cleaning	Equipment cleaning and maintenance [CS39].	8b	6,63E-01	6,95E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Waste management (STP): collection of condensates and other solids or liquids (or sludge) for off-site treatment and disposal or maintenance	Disposal of wastes [CS28]. Equipment cleaning and maintenance [CS39].	8b	3,32E-01	3,48E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Waste management (STP): adsorption/desorption or condensation; anaerobic treatment of wastewater or sludge; Volatil Organic Compounds oxidation	Disposal of wastes [CS28].	3	7,02E-01	1,74E-02
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Waste management (STP): aerobic treatment (activated sludge, extensive aeration)	Disposal of wastes [CS28].	4	7,02E-01	3,48E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	QC laboratory work	Laboratory activities [CS36].	15	4,68E-01	1,74E-01
Substance use as Monomer for Polymerisation (Industrial Application)	Industrial - SU3	Reception of goods / Discharging of vessels, pumping, with sample collection. Storage / Filling of containers	Transfer from/pouring from containers [CS22]. With sample collection [CS56]. Non-dedicated facility [CS82].	8b	2,68E-01	6,95E-01

See Appendix 3.a.3, Appendix 3.b.3 and Appendix 4

10.3.2 Environment

The substance does not meet the criteria for classification as dangerous for the environment but is manufactured/ imported at more than 1000 t/y. Therefore only the risk for man via the environment was assessed. The substance is not classified as toxic (no R48 phrase), not classified as a carcinogen nor mutagen, not toxic to reproduction

(category 1 or 2). Secondary poisoning was considered as not relevant as the substance is not PBT and has no potential to cause toxic effects if accumulated in higher organisms, based on classification data. Risk characterization ratio for man via the environment is provided in paragraph 10.12.

ES 4. Users by workers in industrial settings: Exposure Scenario for the use of the substance for generating energy. (Referred to as Exposure scenario No. 12 in CSR)

Process category (PROC):

PROC 1: Use in closed process, no likelihood of exposure

PROC 2: Use in closed, continuous process with occasional controlled exposure

PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities

PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

PROC 16: Using material as fuel sources, limited exposure to unburned product to be expected

Environmental release category (ERC):

ERC 7: Industrial use of substances in closed systems

Subsequent service life relevant for that use?: no

Exposure Assessment (extracted from Chemical Safety Report)

9.12 Industrial use for generation of energy

9.12.1 Exposure Scenario: Industrial use for generation of energy

Section 1	Exposure Scenario Title
Title	Industrial use for generation of energy - CAS: 80-56-8
Use Descriptor	Sector of Use: SU 3 Industrial Uses.
	Process Categories: PROC1, PROC2, PROC8a, PROC8b, PROC16
	Environmental Release Categories: ERC7 Specific Environmental Release: None (usual on-site RMMs will be considered)
Processes, tasks, activities covered	Industrial use for generation of energy, included : general exposure in close system, storage, cleaning fuel storage tanks, bulk transfers.
Section 2	Operational conditions and risk management measures
Section 2.1	Control of worker exposure
Product characteristics	
Physical form of product	Liquid, vapour pressure 0.5 - 10 kPa [OC4].
Concentration of substance in product	Covers percentage substance in the product up to 100 % (unless stated differently) [G13].

Section 1	Exposure Scenario Title
Title	Industrial use for generation of energy - CAS: 80-56-8
Amounts used	No Limit
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2].
Other Operational Conditions affecting worker exposure	Assumes activities are at ambient temperature (unless stated differently) [G17]. Assumes a good basic standard of occupational hygiene is implemented [G1].
Contributing Scenarios	Risk Management Measures
Number of contributing Scenario:	7
Use in closed process, no likelihood of exposure (Proc1) – General exposure	Handle substance within a closed system [E47]. Chemically resistant gloves (Gloves with available permeation data indicating that the material of construction offers good protection for the substance) with basic employee training. Use suitable eye protection [PPE26].
Use in closed process, no likelihood of exposure (Proc1) – Storage	Store substance within a closed system [E84]. Chemically resistant gloves (Gloves with available permeation data indicating that the material of construction offers good protection for the substance) with basic employee training. Use suitable eye protection [PPE26].
Use in closed, continuous process with occasional controlled exposure (Proc2) – General exposure	Provide extract ventilation to points where emissions occur [E54]. Avoid carrying out activities involving exposure for more than 4 hours [OC28]. Chemically resistant gloves (Gloves with available permeation data indicating that the material of construction offers good protection for the substance) with basic employee training. Use suitable eye protection [PPE26].
Use in closed, continuous process with occasional controlled exposure (Proc2) – Storage	Provide extract ventilation to points where emissions occur [E54]. Avoid carrying out activities involving exposure for more than 4 hours [OC28]. Chemically resistant gloves (Gloves with available permeation data indicating that the material of construction offers good protection for the substance) with basic employee training. Use suitable eye protection [PPE26].
Transfer of chemicals from/to vessels/ large containers at non dedicated facilities (Proc8a) – Cleaning fuel storage tanks.	Provide extract ventilation to points where emissions occur [E54]. Wear full face suitable respiratory protection (conforming to EN140 with Type A filter or better). Chemically resistant gloves (Gloves with available permeation data indicating that the material of construction offers good protection for the substance) with intensive controls. Use suitable eye protection [PPE26].
Transfer of chemicals from/to vessels/ large containers at dedicated facilities (Proc8b) – Bulk transfers (barge, rail, road)	Provide extract ventilation to points where emissions occur [E54]. Avoid carrying out activities involving exposure for more than 4 hours [OC28]. Chemically resistant gloves (Gloves with available permeation data indicating that the material of construction offers good protection for the substance) with basic employee training. Use suitable eye protection [PPE26].

Section 1	Exposure Scenario Title
Title	Industrial use for generation of energy - CAS: 80-56-8
Using material as fuel sources, limited exposure to unburned product to be expected (Proc16) – Use as fuel.	Provide extract ventilation to points where emissions occur [E54]. Chemically resistant gloves (Gloves with available permeation data indicating that the material of construction offers good protection for the substance) with basic employee training. Use suitable eye protection [PPE26].
Section 2.2	Control of environmental exposure
Use of the substance as a fuel in closed systems for industrial uses involves negligible tonnages of substance and hence does not change significantly the regional concentrations. No additional risk for humans via the environment is anticipated from these uses.	
Section 3	Exposure Estimation
Section 3.1 - Health	The ECETOC TRA tool has been used to estimate Tier 1 workplace exposures unless otherwise indicated [G21].
Section 3.2 - Environment	Not relevant for this ES.
Section 4	Guidance to check compliance with the Exposure Scenario
Section 4.1 - Health	Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational Conditions outlined in Section 2 are implemented [G22]. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels [G23].
Section 4.2 - Environment	Not relevant for this ES.

9.12.2 Exposure Estimation: Industrial use for generation of energy

9.12.2.1 Human Health

Exposure Estimation Worker - Industrial use for generation of energy

Generic Exposure Scenario		Contributing Scenarios			Manufacture of the substance (Industrial Application): worker exposure	
Short Title	Life Cycle Stage / Area of Application	Title	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory Exposure (ppm)-	Predicted Dermal Exposure (mg/cm ²)
Industrial use for generation of energy	SU3	Use in closed process, no likelihood of exposure (Proc1) – General exposure	1	ECETOC - TRA	0.010	0.0025

Generic Exposure Scenario		Contributing Scenarios			Manufacture of the substance (Industrial Application): worker exposure	
Short Title	Life Cycle Stage / Area of Application	Title	Process Category (PROC)	Method used for exposure assessment	Predicted inhalatory Exposure (ppm)-	Predicted Dermal Exposure (mg/cm ²)
Industrial use for generation of energy	SU3	Use in closed process, no likelihood of exposure (Proc1) – Storage	1	ECETOC - TRA	0.010	0.0025
Industrial use for generation of energy	SU3	Use in closed, continuous process with occasional controlled exposure (Proc2) – General exposure	2	ECETOC - TRA	0.60	0.001
Industrial use for generation of energy	SU3	Use in closed, continuous process with occasional controlled exposure (Proc2) – Storage	2	ECETOC - TRA	0.60	0.001
Industrial use for generation of energy	SU3	Transfer of chemicals from/to vessels/ large containers at non dedicated facilities (Proc8a) – Cleaning fuel storage tanks.	8a	ECETOC - TRA	0.25	0.0002
Industrial use for generation of energy	SU3	Transfer of chemicals from/to vessels/ large containers at dedicated facilities (Proc8b) – Bulk transfers (barge, rail, road)	8b	ECETOC - TRA	0.90	0.005
Industrial use for generation of energy	SU3	Using material as fuel sources, limited exposure to unburned product to be expected (Proc16) – Use as fuel.	16	ECETOC - TRA	0.50	0.0003

See Appendix 1.a.1 and See Appendix 2.a.11

9.12.2.2 Environment

The substance does not meet the criteria for classification as dangerous for the environment but is manufactured/ imported at more than 1000 t/y.

Use of the substance as a fuel in closed systems for industrial uses involves negligible tonnages of substance and hence does not change significantly the regional concentrations. No additional risk for humans via the environment is anticipated from these uses.

The substance is not classified as toxic (no R48 phrase), not classified as a carcinogen nor mutagen, not toxic to reproduction (category 1 or 2). Secondary poisoning was considered as not relevant as the substance is not PBT and has no potential to cause toxic effects if accumulated in higher organisms, based on classification data.

Risk Characterisation (extracted from Chemical Safety Report)

10.12 Industrial use for generation of energy

10.12.1 Human Health – Workers

Due to the toxicological profile of alpha pinene, no systemic effects are expected after dermal exposure. However, this substance is skin sensitising and a dermal DNEL for local effects was derived to evaluate the remaining risks after RMMs and OCs are implemented. The minimum RMM to protect against skin sensitising properties of substances is gloves (which will be considered for all PROCs).

Apart from those local effects, systemic effects were considered and an inhalation DNEL for systemic long-term effects was calculated for workers.

Local and systemic effects being different toxicological end-points, the risk characterisation ratios calculated for each kind of effect will be considered apart (not added) to decide if the risk is acceptable or not.

Risk characterisation – Worker - Industrial use for generation of energy

Generic Exposure Scenario		Contributing Scenarios		Risk Characterization	
Short Title	Life Cycle Stage / Area of Application	Title	Process Category (PROC)	RCR (systemic inhalation)	RCR (local dermal)
Industrial use for generation of energy	Industrial - SU3	Use in closed process, no likelihood of exposure (Proc1) – General exposure	1	0.010	0.016
Industrial use for generation of energy	Industrial - SU3	Use in closed process, no likelihood of exposure (Proc1) – Storage	1	0.010	0.016

Generic Exposure Scenario		Contributing Scenarios		Risk Characterization	
Short Title	Life Cycle Stage / Area of Application	Title	Process Category (PROC)	RCR (systemic inhalation)	RCR (local dermal)
Industrial use for generation of energy	Industrial - SU3	Use in closed, continuous process with occasional controlled exposure (Proc2) – General exposure	2	0.569	0.006
Industrial use for generation of energy	Industrial - SU3	Use in closed, continuous process with occasional controlled exposure (Proc2) – Storage	2	0.569	0.006
Industrial use for generation of energy	Industrial - SU3	Transfer of chemicals from/to vessels/ large containers at non dedicated facilities (Proc8a) – Cleaning fuel storage tanks.	8a	0.237	0.001
Industrial use for generation of energy	Industrial - SU3	Transfer of chemicals from/to vessels/ large containers at dedicated facilities (Proc8b) – Bulk transfers (barge, rail, road)	8b	0.853	0.031
Industrial use for generation of energy	Industrial - SU3	Using material as fuel sources, limited exposure to unburned product to be expected (Proc16) – Use as fuel.	16	0.474	0.002

See Appendix 3.a.11

10.12.2 Environment

The substance does not meet the criteria for classification as dangerous for the environment but is manufactured/ imported at more than 1000 t/y. Use of the substance as a fuel in closed systems for industrial uses involves negligible tonnages of substance and hence does not change significantly the regional concentrations. No additional risk for humans via the environment is anticipated from these uses.