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Name of product: PHARMA 19 TOTAL S.p.A

UNDERTAKING

VERSION N° 3 OF: 01st JUNE 2015

1.1 PRODUCT IDENTIFIER

PRODUCT NAME : **PHARMA 19** REACH N° : 01-2119487078-27

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Intended Use: Cosmetic, Lubricant, Pharmaceutical, Plastics, Rubber applications, subject to applicable laws and

regulations

Identified Uses:

Distribution of substance

Formulation and (re)packing of substances and mixtures

Use in Coatings - Industrial

Lubricants - Industrial

Metal working fluids / rolling oils - Industrial

Use as binders and release agents - Industrial

Functional Fluids - Industrial

Use in Coatings - Professional

Lubricants - Professional (Low Release)

Lubricants - Professional (High Release)

Metal working fluids / rolling oils - Professional

Use as binders and release agents - Professional

Agrochemical uses - Professional

Use as a fuel - Professional

Functional Fluids - Professional

Use in Coatings - Consumer

Lubricants - Consumer (Low Release)

Lubricants - Consumer (High Release)

Agrochemical uses - Consumer

Use as a fuel - Consumer

Functional Fluids - Consumer

Other Consumer Uses

Uses advised against: This product is not recommended for any industrial, professional or consumer use other than the Identified Uses above.

1. 3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

TOTAL S.p.A.

20090 SEGRATE (MI)



SECTION 2 HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to Regulation (EC) No 1272/2008

Classification : Aspiration toxicant: Category 1. H304: May be fatal if swallowed and enters airways.

2.2 LABEL ELEMENTS:

Pictograms:



Signal Word: Danger

Hazard Statements:

H304: May be fatal if swallowed and enters airways.

Precautionary Statements:

|P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER / doctor/ physician. P331: Do NOT induce

vomiting.

P405: Store locked up.

P501: Dispose of contents and container in accordance with local regulations.

Contains: white mineral oil (petroleum)

2.3 OTHER HAZARDS

Physical / Chemical Hazards: No significant hazards.

Health Hazards: High-pressure injection under skin may cause serious damage. Excessive exposure may result in eye, skin, or respiratory irritation.

Environmental Hazards: No significant hazards. Material does not meet the criteria for PBT or vPvB in accordance with REACH Annex XIII.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCE: This material is defined as a substance UVCB

DESCRIPTION	CAS N°	EINECS N°	%	CLASSIF.GHS/CLP
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White mineral oil (petroleum) 8042-47-5 232-455-8 100 Asp. Tox. 1 H304

REACH N°: 01-2119487078-27

See (M)SDS Section 16 for full text of hazard statements.

3.2 MIXTURE: Not applicable. This product is regulated as a substance

Name of product: PHARMA 19

SAFETY DATA SHEET TOTAL S.p.A

TA SHEET

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SECTION 4 FIRST AID MEASURES

4.1. DESCRIPTION OF FIRST AID MEASURES

EYE CONTACT:

Check for and remove any contact lenses . Immediately flush eyes with running water for at least 5 minutes, keeping eyelids open . If irritation persists, obtain medical advice.

SKIN CONCTACT

Remove contaminated clothing and shoes. Wash contaminated skin thoroughly with plenty of water, using soap if available No adverse effects due to skin contact expected. If product is injected into or under the skin, or into any part of the body, regardless of the appearance of the wound or its size, the individual should be evaluated immediately by a physician as a surgical emergency. Even though initial symptoms from high pressure injection may be minimal or absent, early surgical treatment within the first few hours may significantly reduce the ultimate extent of injury.

INHALATION

Remove from further exposure. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation. INGESTION

Seek immediate medical attention. Do not induce vomiting.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Local necrosis as evidenced by delayed onset of pain and tissue damage a few hours after injection.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

If ingested, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.

PROTECTION OF FIRST- AIDERS:

No action shall be taken involving any personal risk or without suitable training.

See section 11 for more detailed information on health effects and symptoms .

SECTION 5 FIRE-FIGHTING MEASURES

5.1 SUITABLE EXTINGUISHING MEDIA:

Foam, dry chemical powder, carbon dioxide. Water spray /mist may be used

5.1.2 EXTINGUISHING MEDIA WHICH MUST NOT BE USED FOR SAFETY REASONS : water jet , unless used by authorised people . (Stain risk caused by combustion)

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

FIRE AND EXPLOSION HAZARDS

Combustible material , low hazard. The product can form flammable mixtures or can burn only on heating above the flash point. However , minor contamination by hydrocarbons of higher volatility may increase the hazard.

HAZARDOUS COMBUSTION PRODUCTS

Smoke, and carbon monoxide may be formed in the event of incomplete combustion.

5.3 SPECIAL FIRE-FIGHTING PROCEDURES

Water fog or spray, to cool fire-exposed surfaces (e.g. containers) and to protect personnel , should only be used by personnel trained in fire fighting.

Cut off "fuel"; depending on circumstances, either allow the fire to burn out under controlled conditions or use foam or dry chemical powder to extinguish the fire.

Respiratory (SCBA) and eye protection required for fire fighting personnel exposed to fumes or smoke.

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SECTION 6 ACCIDENTAL RELEASE MEASURES

NOTIFICATION PROCEDURES

In the event of a spill or accidental release, notify relevant authorities in accordance with all applicable regulations.

6.1 PERSONAL PRECAUTIONS PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

No action shall be taken involving any personal risk or without suitable training: Put on appropriate personal protective equipment (gloves and protective clothing and boots). Remove contaminated clothes as soon as possible.

6.2 ENVIRONMENTAL PRECAUTIONS:

Shut off source taking normal safety precautions. Prevent liquid from entering sewers, water courses or low lying areas; advise the relevant authorities if it has, or if it contaminates soil /vegetation. Take measures to minimise the effects on ground water.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

SMALL SPILL: Smaller spillage can be wiped up with paper clothes. Normal antistatic work clothes are usually adequate. LARGE SPILL: Recover by skimming or pumping using explosion-proof equipment, or contain spilled liquid with booms, sand, or other suitable absorbent (sand, earth, vermiculite or diatomaceous earth) and remove mechanically into

containers. full body suit of chemical resistant, antistatic material is recommended.

6.4. REFERENCES TO OTHER SECTIONS

See Section 8 and 13.

SECTION 7 HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING:

Handle in accordance with good industrial hygiene and safety practices. Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. Do not ingest; wash hands after handling. If handled at temperatures or with high speed mechanical equipment, vapours or mists might be released and require a well-ventilated workplace. When the material is handled in bulk, an electrical spark could ignite any flammable vapors from liquids or residues that may be present.

The container choice, for example storage vessel, may effect static accumulation and dissipation. Do not store in open or unlabelled containers.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

 $MATERIALS\ AND\ COATINGS\ SUITABLE: Carbon\ steel\ , stainless\ steel\ , polyethylene\ ,\ teflon\ ,\ polypropylene\ Compatibility\ with\ plastic\ materials\ can\ vary\ ;\ we\ therefore\ recommend\ that\ compatibility\ is\ tested\ prior\ to\ use\ .$

LOAD/UNLOAD TEMPERATURE : Ambient (°C : 3 minimum for pumpability) STORAGE TEMPERATURE : Ambient (°C : zero min. to 40 max .)

STATIC ACCUMULATOR: This material is a static accumulator

Store in accordance with local regulations . Store in original container protected from direct sunlight in a dry , cool and well-ventilated area , away from incompatible materials and food and drink .

SPECIAL PRECAUTIONS: Keep containers closed when not in use. Prevent small spills and leakages to avoid slip hazard. Do not eat or drink while working Empty containers may retain residue and can be dangerous. <u>Do not pressurise</u>, cut ,weld ,braze , solder , drill , grind or expose such containers to heat , flame , sparks , static electricity , or other sources of ignition ; they may explode and cause injury or death .

7.3. SPECIFIC END USES:

Section 1 informs about identified end-uses. No industrial or sector specific guidance available.



Name of product: PHARMA 19 TOTAL S.p.A

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

18.1. CONTROL PARAMETERS

OCCUPATIONAL EXPOSURE LIMITS

White mineral oil (petroleum): for oil mists and fume: 5 mg/m3 (8 h) OEL-TWA

5 mg/m3 - ACGIH – TLV

DERIVED NO EFFECT LEVEL (DNEL)/DERIVED MINIMAL EFFECT LEVEL (DMEL)

Worker

Substance Name	Dermal	Inhalation
White mineral oil (petroleum)	220 mg/kg bw/day DNEL, Chronic Exposure,	160 mg/m3 DNEL, Chronic Exposure,
	Systemic Effects	Systemic Effects

Consumer

Substance Name	Dermal	Inhalation	Oral
White mineral oil (petroleum)		35 mg/m3 DNEL, Chronic	40 mg/kg bw/day DNEL,
	Chronic Exposure, Systemic	Exposure, Systemic Effects	Chronic Exposure, Systemic
	Effects		Effects

PREDICTED NO EFFECT CONCENTRATION (PNEC)

C 1 / N	A (C 1	A	A .	C	G 1' 4	C '1	0.1/1
Substance Name	Aqua (fresh	Aqua	Aqua	Sewage	Sediment	Soil	Oral (secondary
	water)	(marine	(intermittent	treatment			poisoning)
		water)	release)	plant			
White mineral oil	NA	NA	NA	NA	NA	NA	NA
(petroleum)							

8.2 EXPOSURE CONTROLS

8.2.1ENGINEERING CONTROLS

Personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of ventilation or other control measures and/or the necessity to use respiratory protective equipment . Reference should be made to EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for the determination of hazardous substances .

8.2.2 PERSONAL PROTECTION

HAND PROTECTION:

In open systems where contact is likely, wear safety goggles, chemical-resistant overalls, and chemically impervious gloves. Suitable gloves are neoprene ,nitrile or acrylonitrile -butadiene rubber or PVC. (Take notice of CEN 420/94, CEN 374/1-3/94 and CEN 388/94)

EYE PROTECTION:

Wear safety goggles/safe shield if splashes may occur. No other special precautions are necessary provided skin/eye contact is avoided.

RESPIRATORY PROTECTION:

If the product is heated under manual handling , use suitable mask with filter A $1\ P2$ or A2P2. Handling in automatic production lines, with exhaust or ventilation , will not require mask.

SKIN AND BODYPROTECTION:

Wear protective clothing if there is a risk of skin contact and change them frequently or when contaminated .

HYGIENIC MEASURES:

Act in accordance with good industrial hygiene and safety practice

ENVIRONMENTAL CONTROLS

See Sections 6, 7, 12, 13.

For Summary of Risk Management Measures across all identified uses, see Annex.

Print date: 26 agosto 2015

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Name of product: PHARMA 19 TOTAL S.p.A

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES 9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE / ODOUR: Clear colourless liquid, neutral odour.

ODOUR: no odour or light petroleum

pH: Not applicable

ODOUR THRESOLD: No data available POUR POINT ASTM D97: - 9 °C

BOILING POINT RANGE ASTM D 86: Data not available

FLASH POINT ASTM D 92 : 184 °C

FLAMMABLE LIMITS (Approximate volume % in air): UEL: 7.0 LEL: 0.9

VAPOR PRESSURE AT 20 °C : max 0,01 kPa VAPOUR DENSITY (air =1) :> 2 kPa at 20 °C

RELATIVE DENSITY ASTM D 4052 AT 15 °C: Not available

SOLUBILITY IN WATER AT 20 °C : Negligible

Log Pow (n-octanol/water partition coefficient) : > 3.5

AUTOIGNITION TEMPERATURE: no data available

DECOMPOSITION TEMPERATURE: no data available

VISCOSITY AT 20 °C ASTM D 445 cPs: 27

VISCOSITY AT 40 °C ASTM D 445 mm2/s : 15

EXPLOSIVE PROPERTIES: None

OXIDIZING PROPERTIES: None

9.2 OTHER INFORMATION

DENSITY AT 15 °C ASTM D 4052 kg/L: 0,84 (approx.)

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SECTION 10 STABILITY AND REACTIVITY

10.1. REACTIVITY: See sub-sections below.

10.2. CHEMICAL STABILITY: Material is stable under normal conditions.

10.3. POSSIBILITY OF HAZARDOUS REACTIONS: Hazardous polymerization will not occur.

10.4. CONDITIONS TO AVOID: Excessive heat. High energy sources of ignition.

10.5. INCOMPATIBLE MATERIALS: Strong oxidizers

10.6. HAZARDOUS DECOMPOSITION PRODUCTS: Material does not decompose at ambient temperatures.

SECTION 11 TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON TOXICOLOGICAL EFFECTS

INHALATION

Acute Toxicity (rat) :4 hours $\ LC\ 50 > 5000\ mg/\ m3$. Minimally Toxic. Test(s) equivalent or similar to OECD Guideline 403

Irritation: Elevated temperatures or mechanical action may form vapours, mists, or fumes witch may be irritating to the eyes, nose, throat and lungs. Avoid breathing vapour, mists, or fumes.

SKIN CONTACT

Acute Toxicity (rabbit) : LD 50 > 5000 mg/m3. Minimally toxic . Test(s) equivalent or similar to OECD Guideline 402 Skin Corrosion/Irritation (Rabbit): Negligible irritation to skin at ambient temperatures. Based on test data for structurally similar materials. Test(s) equivalent or similar to OECD Guideline 404 materials

EYE CONTACT

May cause mild, short-lasting discomfort to eyes . Test(s) equivalent or similar to OECD Guideline $\,405$

INGESTION

Acute Toxicity (rat) : LD 50 > 5000 mg/m3 . Minimally toxic . Test(s) equivalent or similar to OECD Guideline 401 May cause laxative effects when ingested.

SENSITISATION

Respiratory Sensitization: Not expected to be a respiratory sensitizer.

Skin Sensitization: Not expected to be a skin sensitizer. Test(s) equivalent or similar to OECD Guideline 406

ASPIRATION May be fatal if swallowed and enters airways. Based on physic-chemical properties of the material.

CHRONIC EFFECTS

GERM CELL MUTAGENICITY: Not expected to be a germ cell mutagen. Based on test data for structurally similar materials. Test(s) equivalent or similar to OECD Guideline Test method unavailable. $471\ 473\ 474\ 475\ 476$

REPRODUCTIVE TOXICITY: Not expected to be a reproductive toxicant. Based on test data for structurally similar materials Test(s) equivalent or similar to OECD Guideline Test method unavailable. 414 415 416

LACTATION: Not expected to cause harm to breast-fed children.

SPECIFIC TARGET ORGAN TOXICITY (STOT)

Single Exposure: Not expected to cause organ damage from a single exposure.

Repeated Exposure: Not expected to cause organ damage from prolonged or repeated exposure. Based on test data for structurally similar materials. Test(s) equivalent or similar to OECD Guideline Test method unavailable. 407 408 410 411 412 413 452

11.1.13 OTHER INFORMATION

Small amounts of liquid aspirated into the lungs during ingestion or from vomiting may cause chemical pneumonitis or pulmonary edema.

White mineral oil, low viscosity: Did not cause mutations In Vitro. High oral doses in certain strains of rats (F-344) resulted in microscopic inflammatory (microgranuloma) changes in the liver, spleen, and lymph nodes. Some evidence of liver damage was observed. These animals also had some accumulation of saturated mineral hydrocarbons in certain tissues. Similar effects were not observed to the same degree in other rodent strains or in other species.



Name of product: PHARMA 19

TOTAL S.p.A

SECTION 12 ECOLOGICAL INFORMATION

In the absence of specific environmental data for this product, this assessment is based on information for representative products .

- 12.1 ECOTOXICITY: Not expected to be harmful to aquatic organisms
- 12.2 PERSISTENCE AND BIODEGRADATION: This product is expected to be inherently biodegradable
- 12.3 BIOACCUMULATIVE POTENTIAL:

 $Has \ the \ potential \ to \ bioaccumulate \ , \ however \ metabolism \ or \ physical \ properties \ may \ reduce \ the \ bioconcentration \ or \ limit \ bioavailability \ .$

12.4 MOBILITY IN SOIL:

Low solubility and floats and is expected to migrate from water to the land .Expected to partition to sediment and wastewater solids. Low potential to migrate through soil.

12.5 PERSISTENCE, BIOACCUMLATION AND TOXICITY FOR SUBSTANCE .:

This product is not, or does not contain, a substance that is a PBT or a vPvB.

12.6 OTHER ADVERSE EFFECTS: Spill may form a film on water surfaces causing physical damage to organisms. Oxygen transfer could also be impaired.

ECOLOGICAL DATA

Ecotoxicity

Test	Duration	Organism Type	Test Results
Aquatic - Acute Toxicity	96 hour(s)	Fish	LL0 100 - 10000 mg/l: data for similar materials
Aquatic - Acute Toxicity	48 hour(s)	Daphnia magna	EL0 100 mg/l: data for similar materials
Aquatic - Acute Toxicity	72 hour(s)	Pseudokirchneriella subcapitata	EL0 100 mg/l: data for similar materials
Aquatic - Chronic Toxicity	72 hour(s)	Pseudokirchneriella subcapitata	NOELR 100 mg/l: data for similar materials
Aquatic - Chronic Toxicity	21 day(s)	Daphnia magna	NOELR 10 - 1000 mg/l: data for similar materials

Persistence, Degradability and Bioaccumulation Potential

Media	Test Type	Duration	Test Results: Basis
Water	Ready Biodegradability	28 day(s)	Percent Degraded < 60 : similar material

SECTION 13 DISPOSAL CONSIDERATIONS

The generation of waste should be avoided or minimised wherever possible

Empty drums should be taken for recycling, recovery or disposal through a suitably qualified or licensed contractor. Collect and dispose of waste product at an authorised disposal facility, in conformance with national and local regulations and in accordance with EEC Directives on the disposal of waste oil. Do not pressurise, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, static electricity, or other sources of ignition. they may explode and cause injury or death.

13.1. WASTE TREATMENT METHODS

European Waste Code: 13 02 05 | Packaging Waste Code: 15 01 10

NOTE: These codes are assigned based upon the most common uses for this material and may not reflect contaminants resulting from actual use. Waste producers need to assess the actual process used when generating the waste and its contaminants in order to assign the proper waste disposal code.

This material is considered as hazardous waste pursuant to Directive 91/689 ECC, Reglm. 1357/2014 UE on hazardous waste, and subject to the provisions of that Directive unless article1(5) of that Directive applies.

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SECTION 14 TRASPORT INFORMATION

INTERNATIONAL TRANSPORT REGULATIONS

USUAL SHIPPING CONTAINERS:

Rail cars, tank trucks, drums.

14.1 – 14.6 This product is not regulated for carriage according to ADR/RID, IMDG ,ICAO/ IATA

Marine pollutant: not

|14.7 SEA (MARPOL Convention - Annex II):

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not classified according to Annex II

SECTION 15 REGULATORY INFORMATION

15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Applicable EU Directives and Regulations:

1907/2006 [... on the Registration, Evaluation, Authorization and Restriction of Chemicals ... and amendments thereto] 98/24/EC [... on the protection of workers from the risk related to chemical agents at work ...]. Refer to Directive for details of requirements

2004/42/CE [on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC.]

1272/2008 [on classification, labelling and packaging of substances and mixtures.. and amendments thereto] The product is not subjected to Regl. 2037/2000 CE, 850/2004CE, 689/2008 CE

Refer to the relevant EU/national regulation for details of any actions or restrictions required by the above Regulation(s)/Directive(s).

REGULATORY STATUS AND APPLICABLE LAWS AND REGULATIONS

Complies with the following national/regional chemical inventory requirements: AICS, DSL, EINECS, KECI, TSCA, IECSC, PICCS, ENCS

15.2 CHEMICAL SAFETY ASSESSMENT:

REACH Information: A Chemical Safety Assessment has been carried out for the substance(s) that make up this material or for the material itself.

 $EU\ Regulation\ n^{\circ}\ 1907/2006\ Annex\ XIV\ - List\ of\ substances\ subject\ to\ authorisation\ Substances\ of\ very\ high\ concern:$ None of the components are listed

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles: Not applicable

This product is not VOC

Italian poison data base ISS product code: PH19



Name of product: PHARMA 19 TOTAL S.p.A

SECTION 16 OTHER INFORMATION

PRODUCT TYPE / USES

Types of uses according to relevant national or international regulations:

PRODUCTS USED IN COSMETICS and PHARMACEUTICALS as per:

European Pharmacopoeia ,USP, NF, JP, BP, FU, USA and FDA 21 CFR 178.3620(a) and equivalent standards.

EU REGULATIONS

CLASSIFICATION AND LABELLING ACCORDING TO REGULATION EC 1907/2006 AND REGULATION (EC) No 1272/2008

Library of risk phrases listed in this document: H304: May be fatal if swallowed and enters airways.

Abbreviations and acronyms:

ATE : Acute Toxicity Estimate DNEL : Derived No Effect Level

PNEC: Predicted No Effect Concentration
PBT: Persistente, Bioaccumulabile, Tossico
vPvB: very Persistente, very Bioaccumulabile
SVHC: Substances of Very High Concern

VOC : Composto Organico Volatile

 $TLV: Threshold\ Limit\ Value\ (American\ Conference\ of\ Governmental\ Industrial\ Hygienists)$

UVCB: Substances of Unknown or Variable composition, Complex reaction products or Biological materials

ISS: Istituto Superiore della Sanità

LC: Lethal Concentration

LD : Lethal Dose LL : Lethal Loading

EC : Effective Concentration

EL : Effective Loading

NOEC : No Observable Effect Concentration NOELR : No Observable Effect Loading Rate

REFERENCES: Sources of information used in preparing this SDS included one or more of the following: results from in house or supplier toxicology studies, CONCAWE Product Dossiers, publications from other trade associations, such as the EU Hydrocarbon Solvents REACH Consortium, U.S. HPV Program Robust Summaries, the EU IUCLID Data Base, U.S. NTP publications, and other sources, as appropriate.

IDENTIFIED USES:

Distribution of substance (PROC1, PROC15, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9, SU3, SU8, SU9) Use as an intermediate (PROC1, PROC15, PROC2, PROC3, PROC4, PROC8a, PROC8b, SU3, SU8, SU9) Formulation and (re)packing of substances and mixtures (PROC1, PROC14, PROC15, PROC2, PROC3, PROC4, PROC5,

PROC8, PROC9, PROC9, SU10, SU3)

Use in Coatings - Industrial (PROC1, PROC10, PROC13, PROC14, PROC15, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, SU3)

Use in Cleaning Agents - Industrial (PROC1, PROC10, PROC13, PROC2, PROC3, PROC7, PROC8a, PROC8bSU3,) Lubricants - Industrial (PROC1, PROC10, PROC13, PROC17, PROC2, PROC3, PROC4, PROC7, PROC8a, PROC8b, PROC9, SU3)

Metal working fluids / rolling oils - Industrial (PROC1, PROC10, PROC13, PROC17, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, SU3)

 $Use \ as \ binders \ and \ release \ agents - Industrial \ (PROC1, PROC10, PROC13, PROC14, PROC2, PROC3, PROC4, PROC6, PROC7, PROC8a, PROC8b, SU3)$

Functional Fluids - Industrial (PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9, SU3) Use in laboratories - Industrial (PROC15, SU3)

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16. OTHER INFORMATION

Rubber production and processing (PROC1, PROC13, PROC14, PROC15, PROC2, PROC21, PROC3, PROC4, PROC5, PROC6, PROC7, PROC8a, PROC8b, PROC9, SU10)

Polymer processing - Industrial (PROC1, PROC13, PROC14, PROC2, PROC21, PROC3, PROC4, PROC5, PROC6, PROC8a, PROC8b, PROC9, SU10, SU3)

Water treatment chemicals - Industrial (PROC1, PROC13, PROC2, PROC3, PROC4, PROC8a, PROC8b, SU3)

Use in Coatings - Professional (PROC1, PROC10, PROC11, PROC13, PROC15, PROC19, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, SU22)

Use in Cleaning Agents - Professional (PROC1, PROC10, PROC11, PROC13, PROC2, PROC3, PROC4, PROC8a, PROC8b, SU22)

Lubricants - Professional (Low Release) (PROC1, PROC10, PROC11, PROC13, PROC17, PROC18, PROC2, PROC20, PROC3, PROC4, PROC8a, PROC8b, PROC9, SU22)

Lubricants - Professional (High Release) (PROC1, PROC10, PROC11, PROC13, PROC17, PROC18, PROC2, PROC20, PROC3, PROC4, PROC8a, PROC8b, PROC9, SU22)

Metal working fluids / rolling oils - Professional (PROC1, PROC10, PROC11, PROC13, PROC17, PROC2, PROC3, PROC5, PROC8a, PROC8b, PROC9, SU22)

Use as binders and release agents - Professional (PROC1, PROC10, PROC11, PROC14, PROC2, PROC3, PROC4, PROC6, PROC8a, PROC8b, SU22)

Agrochemical uses - Professional (PROC1, PROC11, PROC13, PROC2, PROC4, PROC8a, PROC8b, SU22)

Functional Fluids - Professional (PROC1, PROC2, PROC20, PROC3, PROC8a, PROC9, SU22)

Use in laboratories - Professional (PROC15, SU22)

Explosives manufacture & use (PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b, SU22)

Water treatment chemicals - Professional (PROC1, PROC13, PROC2, PROC3, PROC4, PROC8a, PROC8b, SU22)

Use in Coatings - Consumer (PC01, SU21)

Use in Cleaning Agents - Consumer (PC04, SU21)

Lubricants - Consumer (Low Release) (PC01, SU21)

Lubricants - Consumer (High Release) (PC01, SU21)

Agrochemical uses - Consumer (PC12, SU21)

Use as a fuel - Consumer (PC13, SU21)

Other Consumer Uses (PC28,PC39)

REVISION SUMMARY

DATE OF PREVIOUS ISSUE: 21/07/2014

VERSION: 3

SECTION MODIFIED: Section 1 CAV phone numbers modified; Section 2 (change Precautionary Statements: P301+P310), Section 2 and 3 removed Directive 67/548 CE and 1999/45 CE; Section 8.1 (professional exposure limits), Section 13 (Packaging Waste Code), Section 16.identified uses and Annex exposure scenarios

This MSDS cancels and replaces any preceding release .

In those sections , vertical bars will indicate in the margin the text that has been changed . If a section is listed , but does not show a vertical bar , it indicates that text has been removed .

SOURCE OF KEY DATA

The recommendations presented in this Material Safety Data Sheet were compiled from actual test data (when available), comparison with similar products, component information from suppliers and from recognised codes of good practice.

The information and recommendations contained herein are accurate and reliable as of the date issued, but are offered without guarantee or warranty. They relate to the specific material designated and may not be valid for such material used in combination with any other materials or in any process.

Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy himself as to the suitability and completeness of such information for his own particular use.



16. OTHER INFORMATION

Safety Data Sheet updated in accordance with the provisions of REACH Annex II (EU No 453/2010) and Reglm. 2015/830 UE .

ANNEX

Section 1 Exposure Scenario Title	
Title:	
Distribution of substance	
Use Descriptor	
Sector(s) of Use	SU3, SU8, SU9
Process Categories	PROC1, PROC15, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9
Environmental Release Categories	ERC1, ERC2, ERC3, ERC4, ERC5, ERC6A, ERC6B, ERC6C, ERC6D, ERC7
Specific Environmental Release Category	ESVOC 1.1.v1
=	

Processes, tasks, activities covered

Loading (including marine vessel/barge, rail/road car and IBC loading) and repacking (including drums and small packs) of substance, including its sampling, storage, unloading, distribution and associated laboratory activities.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

General exposures (closed systems) PROC1

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

General exposures (open systems) PROC4

No other specific measures identified.

Process sampling PROC3

No other specific measures identified.

Laboratory activities PROC15

No other specific measures identified.

Bulk transfers (closed systems) PROC8b

No other specific measures identified.

Bulk transfers (open systems) PROC8b

No other specific measures identified.

Drum and small package filling PROC9

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.



Name of product: PHARMA 19

TOTAL S.p.A

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 49 tons/yr

Continuous release.

Emission Days (days/year): 20 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 2400 kg / day Regional use tonnage (tonnes/year): 24000 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0.0001 Release fraction to soil from process (initial release prior to RMM): 1e-005 Release fraction to wastewater from process (initial release prior to RMM): 0

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 90 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 89000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]



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4.2. Environment

Name of product: PHARMA 19

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Section 1 Exposure Scenario Title

Title:

Use as an intermediate

Use Descriptor

Sector(s) of Use

Process Categories

PROC1, PROC15, PROC2, PROC3, PROC4, PROC8a, PROC8b

Environmental Release Categories

ERC6A

Specific Environmental Release Category

ESVOC 1.1.v1

Processes, tasks, activities covered

Use as an intermediate (not related to Strictly Controlled Conditions). Includes incidental exposures during recycling/recovery, material transfers, storage, sampling, associated laboratory activities, maintenance and loading (ncluding marine vessel/barge, road/rail car and bulk container).

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

General exposures (closed systems) PROC1

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

General exposures (open systems) PROC4

No other specific measures identified.

Process sampling PROC3

No other specific measures identified.

Laboratory activities PROC15

No other specific measures identified.

Bulk transfers (closed systems) PROC8b

No other specific measures identified.

Bulk transfers (open systems) PROC8b

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Bulk product storage PROC1

Store substance within a closed system.

Bulk product storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 40 tons/yr

Continuous release.

Emission Days (days/year): 20 days/yr



Name of product: PHARMA 19 TOTAL S.p.A

Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 2000 kg / day Regional use tonnage (tonnes/year): 40 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0

Release fraction to soil from process (initial release prior to RMM): 0.001

Release fraction to wastewater from process (initial release prior to RMM): 1e-005

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 80 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 67000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

This substance is consumed during use and no waste of the substance is generated [ETW5]

Conditions and measures related to external recovery of waste

This substance is consumed during use and no waste of the substance is generated [ERW3]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.





Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Formulation and (re)packing of substances and mixtures	
Use Descriptor	
Sector(s) of Use	SU10, SU3
Process Categories	PROC1, PROC14, PROC15, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9
Environmental Release Categories	ERC2
Specific Environmental Release Category	ESVOC 1.1.v1
Processes, tasks, activities covered	

Formulation, packing and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, mixing, tabletting, compression, pelletisation, extrusion, large and small scale packing, sampling, maintenanance and associated laboratory activities.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

General exposures (closed systems) PROC1

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

General exposures (open systems) PROC4

No other specific measures identified.

Batch processes at elevated temperatures Use in contained batch processes PROC3

No other specific measures identified.

Process sampling PROC3

No other specific measures identified.

Laboratory activities PROC15

No other specific measures identified.

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Mixing operations (open systems) PROC5

No other specific measures identified.

Manual Transfer from/pouring from containers Non-dedicated facility PROC8a

No other specific measures identified.

Drum/batch transfers Dedicated facility PROC8b

No other specific measures identified.

Production of preparations or articles by tabletting, compression, extrusion, pelettisation PROC14

No other specific measures identified.

Drum and small package filling PROC9

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.



Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 24000 tons/yr

Continuous release.

Emission Days (days/year): 300 days/yr
Fraction of EU tonnage used in region: 0.1
Fraction of Regional tonnage used Locally: 1
Maximum daily site tonnage (kg/d): 81000 kg / day
Regional use tonnage (tonnes/year): 24000 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (after typical onsite RMMs consistent with EU Solvent Emissions Directive requirements): [OOC11] 0.0025

Release fraction to soil from process (initial release prior to RMM): 0.0001

Release fraction to wastewater from process (initial release prior to RMM): 5e-006

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, no onsite wastewater treatment required.

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 0 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 18.4 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 2000000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational



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Conditions outlined in Section 2 are implemented. [G22]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Section 1 Exposure Scenario Title	
Title:	
Use in Coatings - Industrial	
Use Descriptor	
Sector(s) of Use	SU3
Process Categories	PROC1, PROC10, PROC13, PROC14, PROC15, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9
Environmental Release Categories	ERC4
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 4.3a.v1
Processes tasks activities covered	

Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including materials receipt, storage, preparation and transfer from bulk and semi-bulk, application by spray, roller, spreader, dip, flow, fluidised bed on production lines and film formation) and equipment cleaning, maintenance and associated laboratory activities.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

General exposures (closed systems) with sample collection PROC1

No other specific measures identified.

General exposures (closed systems) with sample collection PROC2

No other specific measures identified.

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Film formation - force drying, stoving and other technologies Use in contained systems Elevated temperature PROC2

No other specific measures identified.

Film formation - air drying (open systems) PROC4

No other specific measures identified.

Preparation of material for application Mixing operations (closed systems) PROC3

No other specific measures identified.

Preparation of material for application Mixing operations (open systems) PROC5

No other specific measures identified.

Spraying (automatic/robotic) PROC7

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Spraying/fogging by manual application PROC7

Wear a respirator conforming to EN140 with Type A filter or better.

Material transfers Non-dedicated facility PROC8a

No other specific measures identified.

Material transfers Dedicated facility PROC8b

No other specific measures identified.

Roller, spreader, flow application PROC10

No other specific measures identified.

Dipping, immersion and pouring PROC13

No other specific measures identified.

Laboratory activities PROC15

No other specific measures identified.



Name of product: PHARMA 19

TOTAL S.p.A

Material transfers Drum/batch transfers Transfer from/pouring from containers PROC9

No other specific measures identified.

Production of preparations or articles by tabletting, compression, extrusion, pelettisation PROC14

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 1500 tons/yr

Continuous release.

Emission Days (days/year): 100 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 15000 kg / day Regional use tonnage (tonnes/year): 1500 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10

Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0.98 Release fraction to soil from process (initial release prior to RMM): 0

Release fraction to wastewater from process (initial release prior to RMM): 2e-005

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, no onsite wastewater treatment required.

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 90 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 17.7 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 370000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

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3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation, [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Use in Cleaning Agents - Industrial	
Use Descriptor	
Sector(s) of Use	SU3
Process Categories	PROC1, PROC10, PROC13, PROC2, PROC3, PROC7, PROC8a, PROC8b
Environmental Release Categories	ERC4
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 4.4a.v1
Processes, tasks, activities covered	

Covers the use as a component of cleaning products including transfer from storage, pouring/unloading from drums or containers. exposures during mixing/diluting in the preparatory phase and cleaning activities (including spraying, brushing, dipping, wiping, automated and by hand), related equipment cleaning and maintenance.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Automated process with (semi) closed systems Use in contained systems PROC2

No other specific measures identified.

Filling / preparation of equipment from drums or containers Dedicated facility PROC8b

No other specific measures identified.

Use in contained batch processes Automated process with (semi) closed systems Elevated temperature PROC3

No other specific measures identified.

Dipping, immersion and pouring PROC13

No other specific measures identified.

Cleaning with low-pressure washers PROC10

No other specific measures identified.

Cleaning with high pressure washers PROC7

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Manual Surfaces Cleaning No spraying PROC10

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 23 tons/yr

Continuous release.



Name of product: PHARMA 19 TOTAL S.p.A

Emission Days (days/year): 20 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 1100 kg / day Regional use tonnage (tonnes/year): 23 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10
Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to wastewater from process (initial release prior to RMM): 0

Release fraction to air from process (initial release prior to RMM): 1
Release fraction to soil from process (initial release prior to RMM): 0

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 70 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 41000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination.

Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in

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combination.



Section 1 Exposure Scenario Title Title: Lubricants - Industrial **Use Descriptor** Sector(s) of Use SU3 **Process Categories** PROC1, PROC10, PROC13, PROC17, PROC2, PROC3, PROC4, PROC7, PROC8a, PROC8b, PROC9 **Environmental Release Categories** ERC4, ERC7 ESVOC 1.1.v1 ,ESVOC 4.6a.v1 Specific Environmental Release Category

Processes, tasks, activities covered

Covers the use of formulated lubricants in closed and open systems including transfer operations, operation of machinery/engines and similar articles, reworking on reject articles, equipment maintenance and disposal of wastes.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

General exposures (closed systems) PROC1

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

General exposures (open systems) PROC4

No other specific measures identified.

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Filling / preparation of equipment from drums or containers Non-dedicated facility PROC8a

No other specific measures identified.

Initial factory fill of equipment PROC9

No other specific measures identified.

Operation and lubrication of high energy open equipment PROC17

Provide extract ventilation to points where emissions occur.

Manual Rolling, Brushing PROC10

No other specific measures identified.

Treatment by dipping and pouring PROC13

No other specific measures identified.

Spraving PROC7

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Maintenance (of larger plant items) and machine set up Dedicated facility Elevated temperature PROC8b No other specific measures identified.

Maintenance of small items Non-dedicated facility PROC8a

No other specific measures identified.

Remanufacture of reject articles PROC9

No other specific measures identified.

Storage PROC1

Store substance within a closed system.

Storage PROC2



Name of product: PHARMA 19

TOTAL S.p.A

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 100 tons/yr

Continuous release.

Emission Days (days/year): 20 days/yr
Fraction of EU tonnage used in region: 0.1
Fraction of Regional tonnage used Locally: 1
Maximum daily site tonnage (kg/d): 5000 kg / day
Regional use tonnage (tonnes/year): 9300 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10
Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0.0001 Release fraction to soil from process (initial release prior to RMM): 0.001

Release fraction to wastewater from process (initial release prior to RMM): 1e-006

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 70 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 180000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]



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Name of product: PHARMA 19

TOTAL S.p.A

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Metal working fluids / rolling oils - Industrial	
Use Descriptor	
Sector(s) of Use	SU3
Process Categories	PROC1, PROC10, PROC13, PROC17, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9
Environmental Release Categories	ERC4
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 4.7a.v1
Processes, tasks, activities covered	

Covers the use in formulated MWFs (MWFs)/rolling oils including transfer operations, rolling and annealing activities, cutting/machining activities, automated and manual application of corrosion protections (including brushing, dipping and spraying), equipment maintenance, draining and disposal of waste oils.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

General exposures (closed systems) PROC1

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

General exposures (open systems) PROC4

No other specific measures identified.

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Filling / preparation of equipment from drums or containers Dedicated facility PROC8b

No other specific measures identified.

Filling / preparation of equipment from drums or containers Dedicated facility PROC5

No other specific measures identified.

Filling / preparation of equipment from drums or containers Dedicated facility PROC9

No other specific measures identified.

Process sampling PROC3

No other specific measures identified.

Metal machining operations PROC17

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Treatment by dipping and pouring PROC13

No other specific measures identified.

Spraying PROC7

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Manual Rolling, Brushing PROC10

No other specific measures identified.

Automated metal rolling/forming Use in contained systems Elevated temperature PROC2

No other specific measures identified.

Semi-automated metal rolling/forming Elevated temperature PROC17

Provide extract ventilation to points where emissions occur.



Name of product : PHARMA 19

Semi-automated metal rolling/forming PROC4

No other specific measures identified.

Equipment cleaning and maintenance Dedicated facility PROC8b

Drain down system prior to equipment break-in or maintenance.

Equipment cleaning and maintenance Non-dedicated facility PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 100 tons/yr

Continuous release.

Emission Days (days/year): 20 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 5000 kg / day Regional use tonnage (tonnes/year): 190 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0.02

Release fraction to soil from process (initial release prior to RMM): 0

Release fraction to wastewater from process (initial release prior to RMM): 1e-006

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 70 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 180000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

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Name of product: PHARMA 19

TOTAL S.p.A

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Use as binders and release agents - Industrial	
Use Descriptor	
Sector(s) of Use	SU3
Process Categories	PROC1, PROC10, PROC13, PROC14, PROC2, PROC3, PROC4, PROC6, PROC7, PROC8a, PROC8b
Environmental Release Categories	ERC4
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 4.10a.v1 ,ESVOC 8.7c.v1
Processes, tasks, activities covered	

Covers the use as binders and release agents including material transfers, mixing, application (including spraying and brushing) and handling of waste.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

(closed systems) Material transfers PROC1

No other specific measures identified.

Material transfers (closed systems) PROC2

No other specific measures identified.

Material transfers (closed systems) PROC3

No other specific measures identified.

Drum/batch transfers Dedicated facility PROC8b

No other specific measures identified.

Mixing operations (closed systems) PROC3

No other specific measures identified.

Mixing operations (open systems) PROC4

No other specific measures identified.

Dipping, immersion and pouring PROC13

No other specific measures identified.

Mold forming PROC14

No other specific measures identified.

Casting operations (open systems) Elevated temperature PROC6

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Spraying PROC7

Carry out in a vented booth or extracted enclosure.

or

Wear a full face respirator conforming to EN140 with Type A filter or better.

Manual Rolling, Brushing PROC10

No other specific measures identified.

Treatment by dipping and pouring PROC13

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2



Name of product : PHARMA 19 TOTAL

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 51 tons/yr

Continuous release.

Emission Days (days/year): 20 days/yr
Fraction of EU tonnage used in region: 0.1
Fraction of Regional tonnage used Locally: 1
Maximum daily site tonnage (kg/d): 2600 kg / day
Regional use tonnage (tonnes/year): 51 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10
Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 1
Release fraction to soil from process (initial release prior to RMM): 0
Release fraction to wastewater from process (initial release prior to RMM): 0

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 80 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 93000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]



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Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Functional Fluids - Industrial	
Use Descriptor	
Sector(s) of Use	SU3
Process Categories	PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9
Environmental Release Categories	ERC7
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 7.13a.v1
Processes, tasks, activities covered	

Use as functional fluids e.g. cable oils, transfer oils, coolants, insulators, refrigerants, hydraulic fluids in industrial equipment including maintenance and related material transfers.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Bulk transfers (closed systems) PROC1

No other specific measures identified.

Bulk transfers (closed systems) PROC2

No other specific measures identified.

Bulk transfers (closed systems) PROC3

No other specific measures identified.

Drum/batch transfers Dedicated facility PROC8b

No other specific measures identified.

Filling of articles/equipment (closed systems) PROC9

No other specific measures identified.

Filling / preparation of equipment from drums or containers Non-dedicated facility PROC8a

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (open systems) Elevated temperature PROC4

Use dry break couplings for material transfer.

Remanufacture of reject articles PROC9

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 10 tons/yr

Continuous release.



Name of product: PHARMA 19

TOTAL S.p.A

Emission Days (days/year): 20 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 500 kg / day Regional use tonnage (tonnes/year): 140 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10
Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0.0001 Release fraction to soil from process (initial release prior to RMM): 0.001

Release fraction to wastewater from process (initial release prior to RMM): 1e-006

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 0 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 18000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination.

Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in

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combination.



Name of product: PHARMA 19

TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Use in laboratories - Industrial	
Use Descriptor	
Sector(s) of Use	SU3
Process Categories	PROC15
Environmental Release Categories	ERC4
Specific Environmental Release Category	ESVOC 1.1.v1

Processes, tasks, activities covered

Use of the substance within laboratory settings, including material transfers and equipment cleaning.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Laboratory activities PROC15

No other specific measures identified.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 2 tons/yr

Continuous release.

Emission Days (days/year): 20 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 100 kg / day Regional use tonnage (tonnes/year): 10 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10

Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0.025 Release fraction to soil from process (initial release prior to RMM): 0.0001 Release fraction to wastewater from process (initial release prior to RMM): 0.02

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, no onsite wastewater treatment required.

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 0 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 18.4 %

Organisation measures to prevent/limit release from site

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Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 2400 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects. [G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination.

Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Section 1 Exposure Scenario Title

Title:

Rubber production and processing

Use Descriptor

Sector(s) of Use

Process Categories

PROC1, PROC13, PROC14, PROC15, PROC2, PROC21, PROC3, PROC4, PROC5, PROC6, PROC7, PROC8a, PROC8b, PROC9

Environmental Release Categories

ERC1, ERC4, ERC6D

Specific Environmental Release Category

Processes, tasks, activities covered

Manufacture of tyres and general rubber articles, including processing of raw (uncured) rubber, handling and mixing of rubber additives, vulcanising, cooling and finishing.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Assumes use at not more than 20℃ above ambient tem perature[G15]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

(closed systems) Bulk transfers PROC1

No other specific measures identified.

(closed systems) Bulk transfers PROC2

No other specific measures identified.

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Bulk weighing (closed systems) PROC1

No other specific measures identified.

Bulk weighing (closed systems) PROC2

No other specific measures identified.

Small scale weighing Dedicated facility PROC9

No other specific measures identified.

Additive premixing (open systems) PROC3

No other specific measures identified.

Additive premixing (open systems) PROC4

No other specific measures identified.

Additive premixing (open systems) PROC5

No other specific measures identified.

Material transfers Dedicated facility PROC8b

No other specific measures identified.

Material transfers Dedicated facility PROC9

No other specific measures identified.

Calendering (including Banburys) Operation is carried out at elevated temperature (> 20℃ above ambien t temperature). PROC6

No other specific measures identified.

Pressing uncured rubber blanks PROC14

No other specific measures identified.

Tyre build up Spraying PROC7

Minimise exposure by extracted full enclosure for the operation or equipment.



Name of product: PHARMA 19

TOTAL S.p.A

Vulcanisation Operation is carried out at elevated temperature (> 20℃ above ambient temperature). PRO C6 Provide extract ventilation to material transfer points and other openings.

Cooling cured articles Operation is carried out at elevated temperature (> 20℃ above ambient temperature). PROC6

Provide extract ventilation to points where emissions occur.

Production of articles by dipping and pouring PROC13

No other specific measures identified.

Finishing operations PROC21

No other specific measures identified.

Laboratory activities PROC15

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 4300 tons/yr

Continuous release.

Emission Days (days/year): 100 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 43000 kg / day Regional use tonnage (tonnes/year): 4300 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10

Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0.01

Release fraction to soil from process (initial release prior to RMM): 0.0001

Release fraction to wastewater from process (initial release prior to RMM): 1e-005

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, no onsite wastewater treatment required.

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 0 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 18.4 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Prevent discharge of undissolved substance to or recover from wastewater.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1000000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

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Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Polymer processing - Industrial	
Use Descriptor	
Sector(s) of Use	SU10, SU3
Process Categories	PROC1, PROC13, PROC14, PROC2, PROC21, PROC3, PROC4, PROC5, PROC6, PROC8a, PROC8b, PROC9
Environmental Release Categories	ERC4
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 4.21a.v1
Dragonos tooks activities severed	

Processes, tasks, activities covered

Processing of formulated polymers including material transfers, additives handling (e.g. pigments, stabilisers, fillers, plasticisers, etc.), moulding, curing and forming activities, material re-works, storage and associated maintenance.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Bulk transfers (closed systems) PROC1

No other specific measures identified.

Bulk transfers (closed systems) PROC2

No other specific measures identified.

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Bulk weighing (closed systems) PROC1

No other specific measures identified.

Bulk weighing (closed systems) PROC2

No other specific measures identified.

Small scale weighing PROC9

No other specific measures identified.

Additive premixing PROC3

No other specific measures identified.

Additive premixing PROC4

No other specific measures identified.

Additive premixing PROC5

No other specific measures identified.

Calendering (including Banburys) Operation is carried out at elevated temperature (> 20℃ above ambien t temperature). PROC6

Provide extract ventilation to material transfer points and other openings.

Production of articles by dipping and pouring PROC13

No other specific measures identified.

Extrusion and masterbatching PROC14

No other specific measures identified.

Injection moulding of articles PROC14

No other specific measures identified.

Finishing operations PROC21

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.



Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 1900 tons/yr

Continuous release.

Emission Days (days/year): 100 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 19000 kg / day Regional use tonnage (tonnes/year): 1900 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0.1
Release fraction to soil from process (initial release prior to RMM): 1e-005
Release fraction to wastewater from process (initial release prior to RMM): 0

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 80 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of = >= 0.%

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 690000 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

Predicted exposures are not expected to exceed the DN(M)EL when the Risk Management Measures/Operational



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Name of product: PHARMA 19

TOTAL S.p.A

Conditions outlined in Section 2 are implemented. [G22]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19

TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Water treatment chemicals - Industrial	
Use Descriptor	
Sector(s) of Use	SU3
Process Categories	PROC1, PROC13, PROC2, PROC3, PROC4, PROC8a, PROC8b
Environmental Release Categories	ERC3, ERC4
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 3.22a.v1

Processes, tasks, activities covered

Covers the use of the substance for the treatment of water at industrial facilities in open and closed systems

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure
Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Bulk transfers Use in contained systems PROC2

No other specific measures identified.

Drum/batch transfers Dedicated facility PROC8b

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

General exposures (open systems) PROC4

No other specific measures identified.

Pouring from small containers PROC13

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 30 tons/yr

Continuous release.

Emission Days (days/year): 300 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 100 kg / day Regional use tonnage (tonnes/year): 360 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10

Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from process (initial release prior to RMM): 0.05 Release fraction to soil from process (initial release prior to RMM): 0

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Release fraction to wastewater from process (initial release prior to RMM): 0.95

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, no onsite wastewater treatment required.

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 0 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 18.4 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 2400 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination.

Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Use in Coatings - Professional	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC10, PROC11, PROC13, PROC15, PROC19, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b
Environmental Release Categories	ERC8A, ERC8D
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 8.3b.v1
Processes tasks activities covered	

Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including materials receipt, storage, preparation and transfer from bulk and semi-bulk, application by spray, roller, brush, spreader by hand or similar methods, and film formation) and equipment cleaning, maintenance and associated laboratory activities.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Filling / preparation of equipment from drums or containers Dedicated facility PROC8b

No other specific measures identified.

General exposures (closed systems) PROC1

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

Preparation of material for application Mixing operations (closed systems) PROC3

No other specific measures identified.

Film formation - air drying Outdoor. PROC4

No other specific measures identified.

Film formation - air drying Indoor PROC4

No other specific measures identified.

Preparation of material for application Indoor Mixing operations (open systems) Pouring from small containers PROC5

No other specific measures identified.

Preparation of material for application Outdoor. Mixing operations (open systems) Pouring from small containers PROC5

No other specific measures identified.

Material transfers Drum/batch transfers Non-dedicated facility PROC8a

Use drum pumps.

Roller, spreader, flow application Indoor PROC10

No other specific measures identified.

Roller, spreader, flow application Outdoor. PROC10

No other specific measures identified.

Spraying/fogging by manual application Indoor PROC11

Carry out in a vented booth or extracted enclosure.

Spraying/fogging by manual application Outdoor. PROC11

Wear a respirator conforming to EN140 with Type A filter or better.

Dipping, immersion and pouring Indoor PROC13



Name of product: PHARMA 19

TOTAL S.p.A

No other specific measures identified.

Dipping, immersion and pouring Outdoor. PROC13

No other specific measures identified.

Laboratory activities PROC15

No other specific measures identified.

Hand application - finger paints, pastels, adhesives Indoor PROC19

No other specific measures identified.

Hand application - finger paints, pastels, adhesives Outdoor, PROC19

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.059 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 0.16 kg / day Regional use tonnage (tonnes/year): 120 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.98 Release fraction to soil from wide dispersive use (regional only): 0.01

Release fraction to wastewater from wide dispersive use: 0.01

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 5.8 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

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3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1 Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Use in Cleaning Agents - Professional	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC10, PROC11, PROC13, PROC2, PROC3, PROC4, PROC8a, PROC8b
Environmental Release Categories	ERC8A, ERC8D
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 4.4a.v1 ,ESVOC 8.4b.v1
Processes tasks activities covered	<u> </u>

Covers the use as a component of cleaning products including pouring/unloading from drums or containers; and exposures during mixing/diluting in the preparatory phase and cleaning activities (including spraying, brushing, dipping, wiping, automated and by hand).

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Filling / preparation of equipment from drums or containers PROC8a

Avoid carrying out activities involving exposure for more than 1 hour.

Filling / preparation of equipment from drums or containers PROC8b

Avoid carrying out activities involving exposure for more than 1 hour.

Automated process with (semi) closed systems Use in contained systems PROC2

No other specific measures identified.

Automated process with (semi) closed systems Use in contained systems PROC3

No other specific measures identified.

Semi-automated process (e.g.: Semi-automatic application of floor care and maintenance products) PROC4 No other specific measures identified.

Filling / preparation of equipment from drums or containers Non-dedicated facility Outdoor. PROC8a Use drum pumps.

Manual Surfaces Cleaning Dipping, immersion and pouring PROC13

No other specific measures identified.

Cleaning with low-pressure washers Rolling, Brushing PROC10

No other specific measures identified.

Cleaning with high pressure washers Spraying Indoor PROC11

No other specific measures identified.

Cleaning with high pressure washers Spraying Outdoor, PROC11

No other specific measures identified.

Manual Surfaces Cleaning Wiping Rolling, Brushing PROC10

No other specific measures identified.

Degreasing small objects in cleaning station PROC10

No other specific measures identified.

Ad hoc manual application via trigger sprays, dipping, etc. PROC10

No other specific measures identified.

Cleaning of medical devices PROC4

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.



Name of product: PHARMA 19

TOTAL S.p.A

Storage PROC1

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.011 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr
Fraction of EU tonnage used in region: 0.1
Fraction of Regional tonnage used Locally: 1
Maximum daily site tonnage (kg/d): 0.031 kg / day
Regional use tonnage (tonnes/year): 23 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.02 Release fraction to soil from wide dispersive use (regional only): 0 Release fraction to wastewater from wide dispersive use: 1e-006

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1.1 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects, [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]



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Name of product: PHARMA 19

TOTAL S.p.A

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19

TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Lubricants - Professional (Low Release)	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC10, PROC11, PROC13, PROC17,
	PROC18, PROC2, PROC20, PROC3, PROC4, PROC8a,
	PROC8b, PROC9
Environmental Release Categories	ERC9A, ERC9B
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 8.6c.v1 ,ESVOC 9.6b.v1
Processes, tasks, activities covered	

Covers the use of formulated lubricants in closed and open systems including transfer operations, operation of engines and similar articles, reworking on reject articles, equipment maintenance and disposal of waste oil.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

General exposures (closed systems) PROC1

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

Operation of equipment containing engine oils and similar (closed systems) PROC20

No other specific measures identified.

General exposures (open systems) PROC4

No other specific measures identified.

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Filling / preparation of equipment from drums or containers Dedicated facility PROC8b

No other specific measures identified.

Filling / preparation of equipment from drums or containers Non-dedicated facility PROC8a

Avoid carrying out activities involving exposure for more than 1 hour.

Operation and lubrication of high energy open equipment Indoor PROC17

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Operation and lubrication of high energy open equipment Indoor PROC18

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Operation and lubrication of high energy open equipment Outdoor. PROC17

Ensure operation is undertaken outdoors.

Avoid carrying out operation for more than 4 hours.

Limit the substance content in the mixture to 25 %.

Maintenance (of larger plant items) and machine set up Dedicated facility Elevated temperature PROC8b Drain down system prior to equipment break-in or maintenance.

Provide extract ventilation to emission points when contact with warm (> 50℃) lubricant is likely.

Maintenance of small items Non-dedicated facility Elevated temperature PROC8a

Drain or remove substance from equipment prior to break-in or maintenance.

provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).



Name of product : PHARMA 19

Engine Iubricant service PROC9

No other specific measures identified.

Manual Rolling, Brushing PROC10

No other specific measures identified.

Spraying PROC11

Carry out in a vented booth or extracted enclosure.

or

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings. Avoid carrying out activities involving exposure for more than 1 hour.

ΛR

Wear a respirator conforming to EN140 with Type A filter or better.

Treatment by dipping and pouring PROC13

No other specific measures identified.

Storage PROC1

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.058 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 365 kg / day Regional use tonnage (tonnes/year): 120 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.01 Release fraction to soil from wide dispersive use (regional only): 0.01

Release fraction to wastewater from wide dispersive use: 0.01

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 5.7 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

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External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product : PHARMA 19

TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Lubricants - Professional (High Release)	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC10, PROC11, PROC13, PROC17, PROC18, PROC2, PROC20, PROC3, PROC4, PROC8a,
	PROC8b, PROC9
Environmental Release Categories	ERC8A, ERC8D
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 4.7a.v1 ,ESVOC 8.6c.v1 ,ESVOC 9.6b.v1

Processes, tasks, activities covered

Covers the use of formulated lubricants in closed and open systems including transfer operations, operation of engines and similar articles, reworking on reject articles, equipment maintenance and disposal of waste oil.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

General exposures (closed systems) PROC1

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

Operation of equipment containing engine oils and similar (closed systems) PROC20

No other specific measures identified.

General exposures (open systems) PROC4

No other specific measures identified.

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Filling / preparation of equipment from drums or containers Dedicated facility PROC8b

No other specific measures identified.

Filling / preparation of equipment from drums or containers Non-dedicated facility PROC8a

Avoid carrying out activities involving exposure for more than 1 hour.

Operation and lubrication of high energy open equipment Indoor PROC17

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Operation and lubrication of high energy open equipment Indoor PROC18

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.

Operation and lubrication of high energy open equipment Outdoor. PROC17

Ensure operation is undertaken outdoors.

Avoid carrying out operation for more than 4 hours.

Limit the substance content in the mixture to 25 %.

Maintenance (of larger plant items) and machine set up Dedicated facility Elevated temperature PROC8b

Drain down system prior to equipment break-in or maintenance.

Provide extract ventilation to emission points when contact with warm (> 50°C) lubricant is likely.

Maintenance of small items Non-dedicated facility Elevated temperature PROC8a

Drain or remove substance from equipment prior to break-in or maintenance.



provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Engine lubricant service PROC9

Name of product: PHARMA 19

No other specific measures identified.

Manual Rolling, Brushing PROC10

No other specific measures identified.

Spraying PROC11

Carry out in a vented booth or extracted enclosure.

or

Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings. Avoid carrying out activities involving exposure for more than 1 hour.

ΛR

Wear a respirator conforming to EN140 with Type A filter or better.

Treatment by dipping and pouring PROC13

No other specific measures identified.

Storage PROC1

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.058 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 0.16 kg / day Regional use tonnage (tonnes/year): 120 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.005 Release fraction to soil from wide dispersive use (regional only): 0.05

Release fraction to wastewater from wide dispersive use: 0.05

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 5.6 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

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External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Metal working fluids / rolling oils - Professional	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC10, PROC11, PROC13, PROC17, PROC2,
	PROC3, PROC5, PROC8a, PROC8b, PROC9
Environmental Release Categories	ERC8A, ERC8D
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 4.7a.v1 ,ESVOC 8.7c.v1
Processes, tasks, activities covered	

Covers the use in formulated MWFs (MWFs) including transfer operations, open and contained cutting/machining activities, automated and manual application of corrosion protections, draining and working on contaminated/ reject articles, and disposal of waste oils.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

General exposures (closed systems) PROC1

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

Bulk transfers Dedicated facility PROC8b

No other specific measures identified.

Filling / preparation of equipment from drums or containers Dedicated facility PROC8b

No other specific measures identified.

Filling / preparation of equipment from drums or containers Dedicated facility PROC9

No other specific measures identified.

Filling / preparation of equipment from drums or containers Non-dedicated facility PROC8a

Avoid carrying out activities involving exposure for more than 1 hour.

Filling / preparation of equipment from drums or containers Non-dedicated facility PROC5

Avoid carrying out activities involving exposure for more than 1 hour.

Process sampling PROC8b

No other specific measures identified.

Metal machining operations PROC17

provide a good standard of controlled ventilation (10 to 15 air changes per hour).

Avoid carrying out activities involving exposure for more than 4 hours.

Limit the substance content in the mixture to 25 %.

Manual Rolling, Brushing PROC10

No other specific measures identified.

Spraying PROC11

Avoid carrying out activities involving exposure for more than 1 hour.

provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

or

Wear a respirator conforming to EN140 with Type A/P2 filter or better.

Treatment by dipping and pouring PROC13



No other specific measures identified.

Name of product: PHARMA 19

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Equipment cleaning and maintenance PROC8b

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.031 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 0.086 kg / day Regional use tonnage (tonnes/year): 63 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10

Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.005

Release fraction to soil from wide dispersive use (regional only): 0.05

Release fraction to wastewater from wide dispersive use: 0.05

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 3.1 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

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Name of product: PHARMA 19 TOTAL S.p.A

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19

TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Use as binders and release agents - Professional	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC10, PROC11, PROC14, PROC2, PROC3, PROC4, PROC6, PROC8a, PROC8b
Environmental Release Categories	ERC8A, ERC8D
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 4.10a.v1 ,ESVOC 8.10b.v1 ,ESVOC 8.7c.v1

Processes, tasks, activities covered

Covers the use as binders and release agents including material transfers, mixing, application by spraying, brushing, and handling of waste.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

(closed systems) Material transfers PROC1

No other specific measures identified.

Material transfers (closed systems) PROC2

No other specific measures identified.

Material transfers (closed systems) PROC3

No other specific measures identified.

Drum/batch transfers Dedicated facility PROC8b

No other specific measures identified.

Drum/batch transfers Non-dedicated facility PROC8a

Avoid carrying out activities involving exposure for more than 1 hour.

Mixing operations (closed systems) PROC3

No other specific measures identified.

Mixing operations (open systems) PROC4

No other specific measures identified.

Mold forming PROC14

No other specific measures identified.

Casting operations (open systems) Elevated temperature PROC6

Provide extract ventilation to points where emissions occur.

Spraying Machine PROC11

Avoid carrying out activities involving exposure for more than 4 hours.

Spraying Manual PROC11

provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Avoid carrying out activities involving exposure for more than 1 hour.

or

Wear a respirator conforming to EN140 with Type A filter or better.

Manual Rolling, Brushing PROC10

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1



Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.026 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 0.07 kg / day Regional use tonnage (tonnes/year): 51 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.95
Release fraction to soil from wide dispersive use (regional only): 0.025
Release fraction to wastewater from wide dispersive use: 0.025

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 2.5 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]



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Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Agrochemical uses - Professional	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC11, PROC13, PROC2, PROC4, PROC8a, PROC8b
Environmental Release Categories	ERC8A, ERC8D
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 8.11a.v1
Processes tacks activities covered	·

Processes, tasks, activities covered

Use as an agrochemical excipient for application by manual or machine spraying, smokes and fogging; including equipment clean-downs and disposal.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Transfer from/pouring from containers Dedicated facility PROC8b

No other specific measures identified.

Mixing operations (open systems) PROC4

No other specific measures identified.

Spraying/fogging by manual application PROC11

Wear a respirator conforming to EN140 with Type A filter or better.

Spraying/fogging by machine application PROC11

Apply within a vented cab supplied with filtered air under positive pressure and with a protection factor of >20.

Ad hoc manual application via trigger sprays, dipping, etc. PROC13

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.36 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr
Fraction of EU tonnage used in region: 0.1
Fraction of Regional tonnage used Locally: 1
Maximum daily site tonnage (kg/d): 1 kg / day
Regional use tonnage (tonnes/year): 180 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

TOTAL S.p.A

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Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.9

Release fraction to soil from wide dispersive use (regional only): 0.09

Release fraction to wastewater from wide dispersive use: 0.01

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 35 kg / day

Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects. [G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination.

Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Functional Fluids - Professional	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC2, PROC20, PROC3, PROC8a, PROC9
Environmental Release Categories	ERC9A, ERC9B
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 9.13b.v1
Processes tacks activities covered	

Processes, tasks, activities covered

Use as functional fluids e.g. cable oils, transfer oils, insulators, refrigerants, hydraulic fluids in closed professional equipment including incidental exposures during maintenance and related material transfers.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Drum/batch transfers Non-dedicated facility PROC8a

Use drum pumps.

Transfer from/pouring from containers PROC9

No other specific measures identified.

Filling / preparation of equipment from drums or containers PROC9

No other specific measures identified.

Operation of equipment containing engine oils and similar (closed systems) PROC1

No other specific measures identified.

(closed systems) Operation of equipment containing engine oils and similar PROC2

No other specific measures identified.

(closed systems) Operation of equipment containing engine oils and similar PROC3

No other specific measures identified.

(closed systems) Operation of equipment containing engine oils and similar PROC20

No other specific measures identified.

(closed systems) Operation of equipment containing engine oils and similar Elevated temperature PROC20

No other specific measures identified.

Remanufacture of reject articles PROC9

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.011 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr



Name of product: PHARMA 19 TOTAL S.p.A

Fraction of EU tonnage used in region: 0.1
Fraction of Regional tonnage used Locally: 1
Maximum daily site tonnage (kg/d): 0.031 kg / day
Regional use tonnage (tonnes/year): 23 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.05
Release fraction to soil from wide dispersive use (regional only): 0.025
Release fraction to wastewater from wide dispersive use: 0.025

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1.1 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination.

Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Use in laboratories - Professional	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC15
Environmental Release Categories	
Specific Environmental Release Category	ESVOC 1.1.v1
Dungana da la padicidia accessal	·

Processes, tasks, activities covered

Use of small quantities within laboratory settings, including material transfers and equipment cleaning.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Laboratory activities PROC15

No other specific measures identified.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.005 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 0.014 kg / day Regional use tonnage (tonnes/year): 10 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.5 Release fraction to soil from wide dispersive use (regional only): 0 Release fraction to wastewater from wide dispersive use: 0.5

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: 0 %

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

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Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 0.48 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects. [G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Explosives manufacture & use	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC2, PROC3, PROC5, PROC8a, PROC8b
Environmental Release Categories	ERC8E
Specific Environmental Release Category	ESVOC 1.1.v1
Processes, tasks, activities covered	·

Processes, tasks, activities covered

Covers exposures arising from the manufacture and use of slurry explosives (including materials transfer, mixing and charging) and equipment cleaning.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2] Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Bulk transfers Use in contained batch processes PROC3

No other specific measures identified.

Drum/batch transfers Non-dedicated facility PROC8a

Use drum pumps.

Mixing operations (closed systems) PROC3

No other specific measures identified.

Mixing operations (open systems) PROC5

No other specific measures identified.

Material transfers Non-dedicated facility PROC8a

Ensure operation is undertaken outdoors.

Avoid carrying out activities involving exposure for more than 4 hours.

Transfer from/pouring from containers Non-dedicated facility PROC8a

Ensure operation is undertaken outdoors.

Avoid carrying out activities involving exposure for more than 4 hours.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Equipment cleaning and maintenance PROC8b

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Storage PROC2

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.011 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1

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Maximum daily site tonnage (kg/d): 0.031 kg / day Regional use tonnage (tonnes/year): 23 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.001 Release fraction to soil from wide dispersive use (regional only): 0.01 Release fraction to wastewater from wide dispersive use: 0.02

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

No secondary wastewater treatment required.

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 0 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1.1 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination.

Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in combination.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Water treatment chemicals - Professional	
Use Descriptor	
Sector(s) of Use	SU22
Process Categories	PROC1, PROC13, PROC2, PROC3, PROC4, PROC8a, PROC8b
Environmental Release Categories	ERC8F
Specific Environmental Release Category	ESVOC 1.1.v1 ,ESVOC 8.22b.v1
Processes tooks activities covered	·

Processes, tasks, activities covered

Covers the use of the substance for the treatment of water in open and closed systems.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Drum/batch transfers Dedicated facility PROC8b

No other specific measures identified.

General exposures (closed systems) PROC2

No other specific measures identified.

General exposures (closed systems) PROC3

No other specific measures identified.

General exposures (open systems) PROC4

No other specific measures identified.

Pouring from small containers PROC13

No other specific measures identified.

Equipment cleaning and maintenance PROC8a

Drain down system prior to equipment break-in or maintenance.

Storage PROC1

Store substance within a closed system.

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic.

Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 1.5 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 1 Maximum daily site tonnage (kg/d): 4 kg / day Regional use tonnage (tonnes/year): 63 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10

Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.01 Release fraction to soil from wide dispersive use (regional only): 0

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Release fraction to wastewater from wide dispersive use: 0.99

Technical conditions and measures at process level (source) to prevent release

Common practices vary across sites thus conservative process release estimates used.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

If discharging to domestic sewage treatment plant, no onsite wastewater treatment required.

If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of =: >= 0 %

Risk from environmental exposure is driven by

Treat air emissions to provide a typical removal (or abatement?) efficiency of: Not Applicable

Treat onsite wastewater (prior to receiving water discharge) to provide the required removal (or abatement) efficiency of =: >= 18.4 %

Organisation measures to prevent/limit release from site

Do not apply industrial sludge to natural soils.

Sludge should be incinerated, contained or reclaimed.

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 79 kg / day Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs is: 96.6 %

Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Further details on scaling and control technologies are provided in factsheet

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

Required removal efficiency for air can be achieved using on-site technologies, either alone or in combination. Required removal efficiency for wastewater can be achieved using onsite/offsite technologies, either alone or in

combination.



Name of product: PHARMA 19

TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Use in Coatings - Consumer	
Use Descriptor	
Sector(s) of Use	SU21
Process Categories	PROCNA
Environmental Release Categories	ERC8A
Specific Environmental Release Category	ESVOC 1.1.v1
Processes tacks activities acvered	

Processes, tasks, activities covered

Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including product transfer and preparation, application by brush, spray by hand or similar methods) and equipment cleaning.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

No exposure assessment presented for human health. [G39]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.039 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr
Fraction of EU tonnage used in region: 0.1
Fraction of Regional tonnage used Locally: 0.0005
Maximum daily site tonnage (kg/d): 0.11 kg / day
Regional use tonnage (tonnes/year): 78 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.985 Release fraction to soil from wide dispersive use (regional only): 0.005

Release fraction to wastewater from wide dispersive use: 0.01

Technical conditions and measures at process level (source) to prevent release

Not applicable

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Not applicable

Organisation measures to prevent/limit release from site

Not applicable

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

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The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 3.8 kg / day Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3] Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.



Section 1 Exposure Scenario Title

Title:

Use in Cleaning Agents - Consumer

Use Descriptor

Sector(s) of Use

Process Categories

Environmental Release Categories

Specific Environmental Release Category

ESVOC 1.1.v1

Processes, tasks, activities covered

Covers general exposures to consumers arising from the use of household products sold as washing and cleaning products, aerosols, coatings, de-icers, lubricants and air care products.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

No exposure assessment presented for human health. [G39]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.011 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 0.0005 Maximum daily site tonnage (kg/d): 0.031 kg / day Regional use tonnage (tonnes/year): 23 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.95
Release fraction to soil from wide dispersive use (regional only): 0.025
Release fraction to wastewater from wide dispersive use: 0.025

Technical conditions and measures at process level (source) to prevent release

Not applicable

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Not applicable

Organisation measures to prevent/limit release from site

Not applicable

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

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The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1.1 kg / day Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.



Name of product: PHARMA 19

TOTAL S.p.A

SU21
PROCNA
ERC9A
ESVOC 1.1.v1

Processes, tasks, activities covered

Covers the consumer use of formulated lubricants in closed and open systems including transfer operations, application, operation of engines and similar articles, equipment maintenance and disposal of waste oil.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

No exposure assessment presented for human health. [G39]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.011 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 0.0005 Maximum daily site tonnage (kg/d): 0.031 kg / day Regional use tonnage (tonnes/year): 23 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.01 Release fraction to soil from wide dispersive use (regional only): 0.01 Release fraction to wastewater from wide dispersive use: 0.01

Technical conditions and measures at process level (source) to prevent release

Not applicable

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Not applicable

Organisation measures to prevent/limit release from site

Not applicable

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

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The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1.1 kg / day Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.



Name of product: PHARMA 19 TOTAL S.p.A

Section 1 Exposure Scenario Title	
Title:	
Lubricants - Consumer (High Release)	
Use Descriptor	
Sector(s) of Use	SU21
Process Categories	PROCNA
Environmental Release Categories	ERC8A
Specific Environmental Release Category	ESVOC 1.1.v1

Processes, tasks, activities covered

Covers the consumer use of formulated lubricants in closed and open systems including transfer operations, application, operation of engines and similar articles, equipment maintenance and disposal of waste oil.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

No exposure assessment presented for human health. [G39]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.011 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 0.0005 Maximum daily site tonnage (kg/d): 0.031 kg / day Regional use tonnage (tonnes/year): 23 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.005 Release fraction to soil from wide dispersive use (regional only): 0.05 Release fraction to wastewater from wide dispersive use: 0.05

Technical conditions and measures at process level (source) to prevent release

Not applicable

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Not applicable

Organisation measures to prevent/limit release from site

Not applicable

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

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The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1.1 kg / day Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.



Section 1 Exposure Scenario Title	
Title:	
Agrochemical uses - Consumer	
Use Descriptor	
Sector(s) of Use	SU21
Process Categories	PROCNA
Environmental Release Categories	ERC8A
Specific Environmental Release Category	ESVOC 1.1.v1

Processes, tasks, activities covered

Covers the consumer use of agrochemicals in liquid and solid forms.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

No exposure assessment presented for human health. [G39]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.13 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1

Fraction of Regional tonnage used Locally: 0.0005 Maximum daily site tonnage (kg/d): 0.34 kg / day Regional use tonnage (tonnes/year): 63 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10
Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.9 Release fraction to soil from wide dispersive use (regional only): 0.09

Release fraction to wastewater from wide dispersive use: 0.01

Technical conditions and measures at process level (source) to prevent release

Not applicable

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Not applicable

Organisation measures to prevent/limit release from site

Not applicable

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 12 kg / day

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Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.



Name of product: PHARMA 19

TOTAL S.p.A

SU21
PROCNA
ERC9A, ERC9B
ESVOC 1.1.v1
_

Processes, tasks, activities covered

Covers consumer uses in liquid fuels.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

No exposure assessment presented for human health. [G39]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 0.011 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1

Fraction of Regional tonnage used Locally: 0.0005 Maximum daily site tonnage (kg/d): 0.031 kg / day Regional use tonnage (tonnes/year): 23 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10

Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.0001 Release fraction to soil from wide dispersive use (regional only): 1e-005

Release fraction to wastewater from wide dispersive use: 1e-005

Technical conditions and measures at process level (source) to prevent release

Not applicable

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Not applicable

Organisation measures to prevent/limit release from site

Not applicable

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 1.1 kg / day

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Conditions and measures related to external treatment of waste for disposal

Combustion emissions considered in regional exposure assessment [ETW2]

Combustion emissions limited by required exhaust emission controls [ETW1]

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3]

Conditions and measures related to external recovery of waste

This substance is consumed during use and no waste of the substance is generated [ERW3]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.[G23]

4.2. Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.



Section 1 Exposure Scenario Title	
Title:	
Other Consumer Uses	
Use Descriptor	
Sector(s) of Use	
Process Categories	PROCNA
Environmental Release Categories	ERC8A, ERC8D
Specific Environmental Release Category	ESVOC 1.1.v1
Dragonos tooks activities severed	·

Processes, tasks, activities covered

Consumer uses e.g. as a carrier in cosmetics/personal care products, perfumes and fragrances. Note: For cosmetic and personal care products, risk assessment only required for the environment under REACH as human health is covered by alternative legislation.

Section 2 Operational conditions and risk management measures

Section 2.1 Control of worker exposure

Product Characteristic

Liquid

Duration, frequency and amount

Covers daily exposures up to 8 hours (unless stated differently)[G2]

Covers percentage substance in the product up to 100 %[G13]

Other given operational conditions affecting workers exposure

Assumes a good basic standard of occupational hygiene is implemented [G1]

Operation is carried out at elevated temperature (>20 C above ambient temperature)[OC7]

Contributing Scenarios/Specific Risk Management Measures and Operating Conditions

(only required controls to demonstrate safe use listed)

Section 2.2 Control of environmental exposure

Product characteristics

Predominantly hydrophobic. Substance is complex UVCB.

Duration, frequency and amount

Annual site tonnage (tonnes/year): 2.8 tons/yr

Continuous release.

Emission Days (days/year): 365 days/yr Fraction of EU tonnage used in region: 0.1 Fraction of Regional tonnage used Locally: 0.0005 Maximum daily site tonnage (kg/d): 7.7 kg / day Regional use tonnage (tonnes/year): 5600 tons/yr

Environmental factors not influenced by risk management

Local freshwater dilution factor [EF1] 10 Local marine water dilution factor: [EF2] 100

Other given operational conditions affecting environmental exposure

Release fraction to air from wide dispersive use (regional only): 0.95
Release fraction to soil from wide dispersive use (regional only): 0.025
Release fraction to wastewater from wide dispersive use: 0.025

Technical conditions and measures at process level (source) to prevent release

Not applicable

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Not applicable

Organisation measures to prevent/limit release from site

Not applicable

Conditions and measures related to municipal sewage treatment plant

Assumed domestic sewage treatment plant effluent flow is:[STP5] 2000 m3/day

Estimated substance removal from wastewater via domestic sewage treatment is: 96.6 %

Not applicable as there is no release to wastewater.

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The maximum allowable site tonnage (MSafe) based on domestic sewage plant effluent release is: 150 kg / day Conditions and measures related to external treatment of waste for disposal

External treatment and disposal of waste should comply with applicable local and/or national regulations [ETW3] Conditions and measures related to external recovery of waste

External recovery an recycling of waste should comply with applicable local and/or national regulations [ERW1]

Section 3 Exposure Estimation

3.1. Health

The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated [G21]

3.2. Environment

The Hydrocarbon Block Method has been used to calculate environmental exposrue with the Petrorisk model.[EE2]

Section 4 Guidance to check compliance with the Exposure Scenario

4.1. Health

Available hazard data do not enable the derivation of a DNEL for dermal irritant effects. [G32]

Available hazard data do not support the need for a DNEL to be established for other health effects.[G36]

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]

Risk Management Measures are based on qualitative risk characterisation. [G37]

Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. [G23]

4.2. Environment

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures.

