



Extended - SAFETY DATA SHEET

Prepared in accordance with Annex II of the REACH Regulation (EC)1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

BIS-(2-ETHYLHEXYL) PHTHALATE (Diethylphthalate)

Revision: 0 Last up date:

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Substance Identification

Trade name	Diethylphthalate
IUPAC name	Bis-(2-ethylhexyl)phthalate
Synonym	Phthalic acid, bis-(2-ethylhexyl) ester 1,2-Benzenedicarboxylic acid, bis-(2-ethylhexyl) ester
EC#	204-211-0
CAS #	117-81-7
Molecular Formula	C ₂₄ H ₃₈ O ₄
Molecular weight	390.5
REACH Registration number	01-2119484611-38-0008
Chemical characterization	Mono-constituent substance-organic

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

Table1: Uses by workers in industrial settings

Identified Use (IU) name	Use descriptors
Manufacturing and use as intermediate	Process category (PROC): PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises Market sector by type of chemical product: PC 19: Intermediate Environmental release category (ERC):

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	<p>ERC 1: Manufacture of substances</p> <p>Sector of end use (SU):</p> <p>SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals.</p>
<p>Formulation of DEHP in dry-blends and Plastisol formulations</p>	<p>Process category (PROC):</p> <p>PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)</p> <p>Market sector by type of chemical product:</p> <p>PC 32: Polymer preparations and compounds</p> <p>Environmental release category (ERC):</p> <p>ERC 2: Formulation of preparations ERC 3: Formulation in materials</p> <p>Sector of end use (SU):</p> <p>SU 12: Manufacture of plastics products, including compounding and conversion SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals</p>
<p>Polymer processing through compounding, calendering, spread coating, extrusion, injection moulding, low energy manipulations</p>	<p>Process category (PROC):</p> <p>PROC 6: Calendering operations PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation PROC 21: Low energy manipulation of substances bound in materials and/or articles</p> <p>Market sector by type of chemical product:</p> <p>PC 32: Polymer preparations and compounds</p> <p>Environmental release category (ERC):</p> <p>ERC 5: Industrial use resulting in inclusion into or onto a matrix</p> <p>Sector of end use (SU):</p> <p>SU 12: Manufacture of plastics products, including compounding and conversion</p> <p>Article category related to subsequent service life (AC):</p> <p>AC 13: Plastic articles</p>
<p>Use of DEHP as</p>	<p>Process category (PROC):</p>

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laboratory reagent	<p>PROC 15: Use as laboratory reagent</p> <p>Market sector by type of chemical product:</p> <p>PC 32: Polymer preparations and compounds PC 21: Laboratory chemicals</p> <p>Environmental release category (ERC):</p> <p>ERC 1: Manufacture of substances</p> <p>Sector of end use (SU):</p> <p>SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 12: Manufacture of plastics products, including compounding and conversion</p>
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Table2: Uses by professional workers

Identified Use (IU) name	Use descriptors
Polymer processing through low energy manipulations	<p>Process category (PROC):</p> <p>PROC 21: Low energy manipulation of substances bound in materials and/or articles</p> <p>Market sector by type of chemical product:</p> <p>PC 32: Polymer preparations and compounds</p> <p>Environmental release category (ERC):</p> <p>ERC 5: Industrial use resulting in inclusion into or onto a matrix</p>

Table 3: Uses by consumers

Identified Use (IU) name	Use descriptors
Service Life of DEHP contained in articles	<p>Chemical product category (PC):</p> <p>PC 32: Polymer preparations and compounds</p> <p>Environmental release category (ERC):</p> <p>ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release</p> <p>Article category related to subsequent service life (AC):</p> <p>AC 13: Plastic articles</p>
Service life of DEHP contained in medical devices	<p>Chemical product category (PC):</p> <p>PC 32: Polymer preparations and compounds</p> <p>Environmental release category (ERC):</p>

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	<p>ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release</p> <p>Article category related to subsequent service life (AC):</p> <p>AC 13: Plastic articles AC 0: Other: Medical Devices</p>
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Uses advised against

Tabel 4: Uses by consumers advised against

Use advised against name	Use descriptors
Use as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles.	<p>Chemical product category (PC):</p> <p>PC 32: Polymer preparations and compounds</p> <p>Article category related to subsequent service life (AC):</p> <p>AC 01: Other (non intended to be released): Toys and childcare articles</p> <p>Remarks: Restriction under regulation 1907/2006</p>
Use in substances and preparations placed on the market for sale to the general public (see Restriction 30 Annex XVII REACH)	Remarks: See specific conditions in restriction 30 Annex XVII REACH

1.3. Details of the supplier of the safety data sheet

Name	S.C. OLTCHIM S.A
Address	1 Uzinei Street, 240050 Ramnicu Valcea, Romania
Phone N°	+40 250 701 200
FAX N°	+40 250 735 030
E-mail of competent person responsible for SDS in the MS or in the EU:	tehnich@oltchim.ro

1.4. Emergency telephone

European Emergency N°:	112
Emergency telephone at the company:	+40/250/738141
Available outside office hours:	24h/day/365days

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2. HAZARD IDENTIFICATION

2.1. Classification of the substance

2.1.1. Classification according to Regulation (EC) 1272/2008

Repr. 1B: H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.)
Route of exposure: Oral

2.1.2. Classification according to Directive 67/548/EEC

Repr. Cat. 2; R60

Repr. Cat. 2; R61

2.2. Label elements

2.2.1. Labeling according to Regulation (EC) 1272/2008

Signal word: Danger

Hazard pictogram:

GHS08: health hazard



Hazard statements:

H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

Route of exposure: Oral

Precautionary statements:

P201: Obtain special instructions before use.

P281: Use personal protective equipment as required.

P308+P313: IF exposed or concerned: Get medical advice/attention.

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2.2.2. Labeling according to Directive 67/548/EEC

Indication of danger:

T - toxic

R-phrases:

R60 - may impair fertility

R61 - may cause harm to the unborn child

S-phrases:

S53 - avoid exposure - obtain special instructions before use

S45 - in case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

2.3. Other effects

The substance does not meet the criteria for PBT or vPvB substance.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	PBT/vPvB	CAS no/EC No/REACH No.	Classification according to Reg (EC) No. 1272/2008	Classification according to D 67/548/EC	Concentration (%)
Bis-(2-ethylhexyl) phthalate	No/No	117-81-7/204-211-0/ 01-2119484611-38-0008	Repr. 1B: H360	Repr. Cat. 2; R60 Repr. Cat. 2; R61	Min.99.5

Impurities

No impurities relevant for classification and labeling.

See section 16 for the full text of the R phrases and H-statement declared above

4. FIRST - AID MEASURES

4.1 Description of first aid measures

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General Advice: IF exposed or if you feel unwell: Call a Poison Center or doctor/physician. Show this safety data sheet to the doctor in attendance.

If inhaled: Inhalation of mist can cause nausea and is irritating to the respiratory tract. Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult give oxygen. Call a physician.

In case of skin contact: Wash the contaminated skin with plenty of soap or mild detergent and water for at least 15 minutes while removing contaminated clothing and shoes. If irritation persists after washing, get medical attention.

In case of eye contact: Wash the eyes immediately with large amount of water lifting the upper and lower lids, until no evidence of chemical remains at least 15-20 minutes. If irritation persists after washing get medical attention. Contact lenses should not worn with this product.

In case of ingestion: If swallowed do not induce vomiting. Give large quantities of water. Never give anything by mouth to an unconscious person. Get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

By eye contact: May cause mild eye irritation. Causes redness and pain.

By skin contact: May cause mild skin irritation

By ingestion: May cause gastrointestinal irritation with nausea, vomiting and diarrhea. May cause central nervous system depression.

By inhalation: Material has a low vapor pressure, so exposure to vapor is not likely. Exposure to dioctyl phthalate occurs from spray or mist, rather than from the vapor, unless heat is applied. If the product is heated, misted or sprayed, it may cause irritation of the respiratory tract if inhaled.

Chronic effects:

DEHP toxicity appears to be a high-dose phenomenon readily demonstrable in some but not all rodent species and strains. Liver toxicity, so characteristic of rodent responses to DEHP, appears to be irrelevant to humans. May impair fertility. May cause harm to the unborn child.

DEHP has not been found to induce skin or respiratory sensitisation in animals.

Absorbtion rate of DEHP throught the skin: 5%

4.3 Indication of immediate medical attention and special treatment needed

Treat symptomatically and supportively.

5. FIRE - FIGHTING MEASURES

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5.1 Extinguishing media

Suitable extinguishing media: Dry chemical, foam or carbon dioxide and water spray.

Unsuitable extinguishing media: None

5.2 Special hazards arising from the substance or mixture

Exposure hazards: As organic substance DEHP is combustible. Vapors may be heavier than air. They can spread along the ground and collect in low or confined areas. Run off from fire control or dilution water may cause pollution. Use water-spray to cool fire exposed containers. Prevent entry into sewers and water courses of the wastes resulted from fire.

Hazardous combustion products: Decomposition products may include the following materials: carbon dioxide, carbon monoxide

5.3 Advice for firefighters

Special precautions for fire-fighters: Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

Protection of fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for firefighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

Remarks : Use water spray to keep fire-exposed containers cool.

6. ACCIDENTAL RELEASE MEASURES

6.1 . Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Keep unnecessary and unprotected personnel away from entering. Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8). Do not touch or walk through spilt material. Shut off all ignition sources.

For emergency responders: Ventilate area of leak or spill. Persons performing clean-up work should wear adequate personal protective equipment and a self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode. Remove all sources of ignition.

6.2. Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers,

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waterways, soil or air). Contain and recover liquid when possible. Keep closed containers and dispose according to all applicable federal, state or local environment regulations

6.3. Methods and materials for containment and cleaning up

Methods of cleaning up: Absorb spills with dry sand, earth or similar non-combustible absorbent material then place into suitable container for later disposal. For large, dike and pump into suitable containers for disposal. Flush area with plenty of water. Waste water will be treated in biological treatment plant.

Special precautions: Do not use combustible materials, such as saw dust. Do not flush to sewer!

6.4 Reference to other sections

Additional advice: Refer to section 8, 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Protective measures: Protect containers from physical damage. The personnel which handling the product must wear protective equipment. Sources of ignition such as smoking and open flames prohibited where bis-(2-ethylhexyl)phthalate is handled.

Advice on general occupational hygiene: Avoid inhalation or ingestion and contact with skin and eyes. General occupational hygiene measures are required to ensure safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no drinking, eating and smoking at the workplace. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home.

7.2. Conditions for safe storage, including any incompatibilities

Store in a tightly closed containers in a cool, dry, well ventilated area away from sources of heat, moisture and incompatible substances. Containers of this material may be hazardous when empty since they retain product residues (vapors, liquid).

Incompatible: Strong oxidizers, strong bases, acids.

Incompatible materials for storage: PVC.

7.3. Specific end use(s)

Please check the identified uses from Section 1.2.

For more information please see the relevant exposure scenario, available via your supplier/given in the Annex I.

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8 . EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limit (OEL), 8 h TWA: 5 mg/m³

Short-term exposure limit (STEL), 15 min: -

8.2 DNEL values:

Exposure pattern	Route	Descriptor	DNEL / DMEL	((Corrected) Dose descriptor *)
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	9.6 mg/kg bw/day	NOAEL: 288.0 mg/kg bw/day
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	4.5 mg/m ³	NOAEC: 33.8 mg/m ³

8.3. Exposure control

Engineering control : A system of local and/or general exhaust is recommended to keep employee exposure as low as possible. Local exhaust ventilation is generally preferred because it can control the emission of the contaminant at its sources, preventing dispersions of it into the general work area.

Personal protective equipment

Respiratory protection: For conditions of use where exposure to substance is apparent, consult an industrial hygienist. For emergencies or instances where the exposure level are not known, use a full face piece positive pressure air-supplied respirator.

Hand protection: Wear rubber gloves.

Eye / Face protection: Use chemical safety goggles and/or full face shield where splashing is possible. Maintain eye wash and quick-drench facilities in work area.

Skin protection: Wear impervious protective clothing , including boots, gloves, lab coat apron or coveralls as appropriate, to prevent skin contact.

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Other precautions: Maintain shower, eye wash fountain and quick-drench facilities in work area.

9. PHYSICAL AND CHEMICAL PROPERTIES

General informations

Appearance	Clear oil liquid
Odor	Characteristic odour

Important health, safety and environmental informations

Boiling point	384°C at 1 atm. pressure
Flash point	above 200°C
Flammability	not flammable
Explosive properties	not explosive
Oxidizing properties	no oxidizing properties
Vapor pressure, 20 °C	1,0x10 ⁻⁷ mmHg
Specific gravity (water=1)	0.98 at 20°C
Solubility-water	0.003 mg/L at 20 °C
-organic solvents	miscible with most common solvents
Partition coefficient (log K _{ow})	9.64
Dynamic viscosity	81 mPa s (dynamic) at 20 °C

Other informations

Melting point	-47°C
Autoignition temperature	not applicable

10 . STABILITY AND REACTIVITY

10.1. Reactivity: No specific test data related to reactivity available for this product. Hazardous polymerization will not occur.

10.2 Chemical stability: Stable under ordinary conditions of use and storage.

10.3 Possibility of hazardous reactions: Reacts with strong oxidizing agents.

10.4 Conditions to avoid: heat, flame, source of ignition and incompatibles.

10.5 Incompatible materials: PVC, Strong oxidizers, strong bases, acids, nitrates.

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11. TOXICOLOGICAL INFORMATION

	Conclusions
Absorbtion	Absorption rate of DEHP through the skin: 5%
Acute toxicity	Oral: LD0 (rat): > 20000 mg/kg bw (male/female) Dermal: LD50 (rabbit) : 19800 mg/kg bw Inhalation: LC0 (rat) > 10620 mg/m ³ air (nominal) (male/female)
Irritation/Corrosion	Skin irritation / corrosion: slightly irritating Eye irritation: slightly irritating
Sensitisation	Skin: not sensitizing Respiratory: DEHP is not considered as a respiratory sensitizer
Repeated dose toxicity	Oral: NOAEL = 4.8 mg/kg bw/day Inhalation: NOAEC= 50 mg/m ³ air (rat-male/female) Dermal: NOAEL = 50 mg/kg bw/day (rat/mal)
Mutagenity	Genetic toxicity: negative
Carcinogenity	According to the criteria edicted in REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008, no classification is warranted for carcinogenicity.
Toxicity for reproduction	For developmental effects, the NOAEL is 100 ppm (4.8 mg/kg bw/d) and the LOAEL is 1000 ppm (14 mg/kg bw/d), based on effects on the male reproductive organs. Reprotoxic 1B : Regulation (EC) No 1272/2008 Annex VI Table 3.1

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

The very low water solubility of DEHP causes problems when testing toxicity to aquatic organisms and when interpreting the results. Most aquatic studies with DEHP have been made at test levels, which exceed the water solubility of 3 µg/l.

Short-term toxicity to fish

Pimephales promelas and *Oryzias latipes*/fresh water: LC50 (96 h): > 0.326 mg/L

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Brachydanio rerio (new name: Danio rerio)/fresh water/ semi-static: LC0 (96 h) > 100 mg/L

From the short-term toxicity studies it can be concluded that DEHP has no acute effect on fish at concentrations far exceeding its water solubility.

Long-term toxicity to fish

By exposure to concentrations in DEHP well above water solubility, there is no adverse effect on fish. Hence, there is no reliable long-term study indicating effects below the “apparent” water solubility of DEHP nor when administered via the food. Therefore, it is not considered suitable to specify a chronic NOEC for fish exposed via water or food.

Short-term toxicity to aquatic invertebrates

Daphnia magna/fresh water/static (according to OECD Guideline 202) EC50 (48 h): ≥ 0.003 mg/L

Long-term toxicity to aquatic invertebrates:

As conclusion, considering all available data no value could be set to use as NOEC for aquatic invertebrates. Therefore it is impossible to determine whether any effects observed in the toxicity tests may be relevant to use for derivation of a PNEC for water.

Algae and aquatic plants

Pseudokirchnerella subcapitata (algae)/fresh water EC50 (72 h): > 0.003 mg/L

Toxicity to sediment

Freshwater PNEC sediment is therefore 100 mg/kg dw

Marine water PNEC sediment is therefore 10 mg/kg dw

Toxicity to soil macro-organisms

DEHP showed no acute toxicity to earthworm at the limit concentration of 1000 mg/kg (dw)

Toxicity to terrestrial plants:

DEHP is not harmful to plants.

Toxicity to birds:

Long-term EC10/LC10 or NOEC for birds: 1700 mg/kg food (for reproductive effect)

PNEC oral (secondary poisoning) = 3.3 mg/kg food.

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12.2. Persistence and degradability: Substance is readily biodegradable: 82 % in 28 days, (OECD 301B modified sturm test).

Half lives estimated on reliable and environmentally relevant criteria are as follows:

Environmental compartment	Route	Rate (d-1)	Half-life (d)	Half life (h)
Surface water and sediment	Biodegradation (aerobic)	0.2-2.0	3.5-0.35	84-8.4
Soil	Biodegradation (aerobic)	0.01-0.1	69-7	1663-166
Soil and sediments	Biodegradation (anaerobic)	0.006-0.1	116-69	2784-1656
Wastewater	Slurry phase	0.75	0.92	22
Air	Photolysis (indirect)	3.5-1.2	0.6-0.3	14.4-7.2

In water and sediment, it is shown that DEHP is readily biodegradable under aerobic conditions but not biodegradable under anaerobic conditions.

12.3. Bioaccumulative potential: Based on its log Kow of 7.5 DEHP should have potential for bioaccumulation. However, based on multiple bioaccumulation studies in aquatic and terrestrial systems, DEHP does not bioaccumulate.

Based on multiple bioaccumulation studies in aquatic systems, it appears that DEHP does not bioaccumulate and even shows food web biomagnifications factor below 1 indicating a trophic dilution. Moreover in terrestrial environment, DEHP is not bioaccumulated neither by plants nor by soil organisms.

12.4. Mobility

Air: As volatilization DEHP is very limited at ambient temperature, and half-life in the atmosphere is of 1 day due to phototransformation, DEHP may not contaminate the air compartment.

Water: Although not soluble in water (3µg/L) the hydrolysis and photolysis of DEHP are not expected in water. With a high potential of adsorption (Log Kow = 7.5; Log Koa=10.5 and Koc estimated at 165,000) the equilibrium for DEHP is in favor of particles. Thus the transport of DEHP in aquatic environments will to a high degree depend on the transport of particles.

Soil and sediments: Therefore final compartments for DEHP is expected to be sediments and soils. From biodegradation studies in soil, slow mineralization rate is observed under environmental conditions with a half life time of 150 days at room temperature and about 300 days at 10°C.

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12.5. Results of PBT and vPvB assessment: DEHP has not been found to meet the PBT or vPvB criteria.

PBT : No.

P: No. B: No. T: Yes.

vPvB : No.

vP: No. vB: No

13. DISPOSAL CONSIDERATIONS

This section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

13.1.1 Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spill material and runoff and contact with soil, waterways, drains and sewers.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

13.1.2. Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spill material and runoff and contact with soil, waterways, drains and sewers.

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14. TRANSPORT INFORMATION

15. REGULATORY INFORMATION

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Substances of very high concern (Authorizations): DEHP is listed

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Restrictions on use: see Restriction 30 from Anex XVII.

Other EU regulations: DEHP is a SEVESO substance, not ozone depleting substance and not a persistent organic pollutant.

15.2 Chemical safety Assessment Assessment

A chemical safety assessment has been carried out for this substance.

16. OTHER INFORMATION

16.1. Full text of H-Statements referred to under sections 2 and 3

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H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

Route of exposure: Oral

16.2 Full text of R-phrases referred to under sections 2 and 3

R60 - may impair fertility

R61 - may cause harm to the unborn child

16.3. Full text of P-Statements referred to under sections 2 and 3.

P201: Obtain special instructions before use.

P281: Use personal protective equipment as required.

P308+P313: IF exposed or concerned: Get medical advice/attention.

16.4. Full text of S-Statements referred to under sections 2 and 3.

S53 - avoid exposure - obtain special instructions before use

S45 - in case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

16.5. Explanations for possible abbreviations mentioned in above sections

PBT: Persistent, bioaccumulative and toxic.

vPvB: Very persistent and very bioaccumulative.

ES: Exposure Scenario

WGK: Wassergefährdungsklasse (Water hazard class)

DNEL: Derived No Effect Level

PNEC: Predicted No-Effect Concentration

ADR: European **Agreement** concerning the International Carriage of **Dangerous** Goods by **Road**

RID: **International** Carriage of **Dangerous** Goods by **Road**

IMDG Code: International Maritime Dangerous Goods Code

ICAO/IATA: International Civil Aviation Organization/ International Air Transport Association.

16.6. Revision: Revision 0

Annex I to SDS- Exposure Scenario

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Disclaimer:

Oltchim provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. The information is intended to aid the user in controlling the handling risks; it is not to be construed as a warranty or specification of the product quality. The information may not be or may not altogether be applicable to combinations of the product with other substances or to particular applications. The user is responsible for ensuring that appropriate precautions are taken and for satisfying themselves that the data are suitable and sufficient for the product's intended purpose. In case of any unclarity we advise consulting the supplier or an expert.

ANNEX I –EXPOSURE SCENARIO

1. Exposure scenario 1: Manufacturing, distribution and use of DEHP as intermediate (Ziegler Natta catalyst)

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This scenario covers all the industrial activities associated with manufacturing, distribution and use of DEHP as intermediate (Ziegler Natta catalysts). Included within this scenario are material receipt, preparation, reaction, sampling, bulk transfer and storage, as well as equipment cleaning and associated maintenance activities. All these activities take place on industrial sites with mainly confined dedicated equipment.

1.1. Exposure scenario

<i>Section 1</i>	<i>Exposure Scenario Title</i>
Title	Manufacture and distribution and use as intermediate
Sector of Use	SU3, 8, 9
Process Category	PROC1, PROC2, PROC3, PROC4, PROC8b
Product Category	19
Article Category	n/a
Environmental release Category	ERC1
Specific environmental release category	n/a
Processes, tasks, activities covered	Covers the manufacture, sampling, bulk transfer, storage, distribution, material receipt, loading, cleaning and maintenance activities with the substance in the Process Categories listed above.
<i>Section 2</i>	<i>Operational conditions and risk management measures</i>
<i>Section 2.1</i>	<i>Control of worker exposure</i>
Product characteristics	
Physical form of product	Liquid
Volatility	Very low volatility
Concentration of substance in product	Up to 100%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2].
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes activities are at ambient temperature (unless stated differently) [G17]. Assumes a good basic standard of occupational hygiene is implemented [G1].

<i>Risk Management Measures</i>			
<i>Identi-</i>	<i>Contributing</i>	<i>Process</i>	<i>Risk Management Measures</i>

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<i>fier*</i>	<i>Scenarios</i>	<i>Categorie s</i>	
ES1-W1	General exposures (closed systems); Outdoors, No LEV present.	1	Handle substance within a closed system [E47]. Ensure operation is undertaken outdoors [E69]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES1-W2	General exposures (closed systems); With sample collection; Outdoors, No LEV present.	2	Handle substance within a closed system [E47]. Ensure operation is undertaken outdoors [E69]. Sample via a closed loop or other system to avoid exposure [E8]. Avoid carrying out operation for more than 1 hour [OC11]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES1-W3	General exposures (closed systems); With sample collection; Indoors, with LEV present.	2	Handle substance within a closed system [E47]. Provide extract ventilation to material transfer points and other openings [E82]. Avoid carrying out operation for more than 1 hour [OC11]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES1-W4	Use in contained batch processes; With sample collection; Outdoors, No LEV present.	3	Handle substance within a closed system [E47]. Ensure operation is undertaken outdoors [E69]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES1-W5	Use in contained batch processes; Drum/batch transfers; With sample collection; Indoors, No LEV present.	4	Avoid carrying out operation for more than 1 hour [OC11]. Drain down and flush system prior to equipment break-in or maintenance [E55]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]; Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES1-W6	Drum/batch transfers; Dedicated facility; Outdoors.	8b	Transfer via enclosed lines [E52]. Ensure operation is undertaken outdoors [E69]. Avoid carrying out operation for more than 4 hour [OC12]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with specific activity training. [PPE17]
ES1-W7	Drum/batch transfers; Dedicated facility; Indoors, with LEV present.	8b	Transfer via enclosed lines [E52]. Provide extract ventilation to material transfer points and other openings [E82]. Avoid carrying out operation for more than 4 hour [OC12]. Wear chemically resistant gloves (tested to EN374) in combination with specific activity training.

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[PPE17].

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

Section 2	Operational conditions and risk management measures						
Section 2.2	Control of environmental exposure						
Identifier*: Manufacturing Site	ES1-E1	ES1-E2	ES1-E3	ES1-E4	ES1-E5	ES1-E6	ES1-E7
Contributing scenario	Manufacturing						
Environmental Release Category	ERC1						
Specific ERC	-						
Assessment scenario	Based on measured data from 7 European producers						
Operational Conditions							
Amounts used	Total production volume : 204,05 kt/y						
Amounts produced in the EU (ktonnes/year)	37.6	36	31.4	16.1	37.3	36.6	9.05
Fraction of tonnage for application (%)	18.4	17.6	15.4	7.9	18.3	17.9	4.6
Fraction of main local source (%)	100						
Fraction of substance in end-use products (%)	100						
Frequency and duration of use							
Type of release (C= continuous, B=batch)	C	C	B	B	C	C	C
Emission days (days/year)	220	350	350	80	333	333	249
Daily amount in 2009 (tonnes per day)	171	103	90	201	112	110	36
Environmental factors not influenced by risk management							
Release fraction in fresh/marine water	1.62E-07	5.38E-08	5.01E-09	3.84E-09	5.76E-06	3.00E-11	1.16E-07
Local marine water dilution factor	One producer (see above for release fraction)						
Release fraction in air	0 (def)	8.99E-08	4.77E-06	2.8E-07	8.84E-07	3.98E-07	8.66E-07
Release fraction in soil	0	0	0	0	0	0	0
Other given operational conditions affecting environmental exposure							
Industry category	2 Chemical Industry : Basic chemicals						
Use category	33 Intermediate						
Main category production	Ib Inter stored on site. Stored on site/ cont. prod						
Main category industrial use	nr						
Extra details on use category	nr						
Emission tables	A1.1 (general table), B1.5 (general table)						

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Risk Management Measures	
Water	
On site wastewater treatment techniques	All producers treat their WW on-site via mechanical and/or biological treatments. Collect all waste waters and spillages for treatment by WWTP or other suitable system. Discharge to aquatic environment is restricted by the Water Framework Directive[TCS2]
Conditions and measures related to municipal sewage treatment plant	Not applicable
Estimated substance removal from wastewater via domestic sewage treatment (%)	Not applicable
Conditions and measures related to external treatment of waste for disposal (including sludge)	Incineration or disposal as industrial waste
Soil	Soil emission controls are not applicable as there is no direct release to soil. [TCR4]
Air	Negligible air emissions as process operates in a contained system.[OOC21]
Other environmental control measures additional to above	External treatment and disposal of waste should comply with applicable local and/or national regulations. [ETW3]

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

2. Exposure scenario 2: Formulation of DEHP in dry-blend and Plastisol formulations

This scenario covers all the industrial activities associated with formulation of DEHP in dry blends (solid formulations) and Plastisol (liquid formulation). Included within this scenario are material receipt, preparation,

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reaction, bulk transfer and storage, as well as equipment cleaning, and associated maintenance activities. All these activities take place on industrial sites with mainly confined equipment.

2.1. Exposure scenario

<i>Section 1</i>	<i>Exposure Scenario Title</i>
Title	Formulation of DEHP in dry-blend and Plastisol formulations
Sector of Use	SU3, SU8, SU10, SU12
Process Category	PROC1, PROC2, PROC3, PROC5, PROC8b
Product Category	32
Article Category	nr
Environmental release Category	ERC2, ERC3
Specific environmental release category	n/a
Processes, tasks, activities covered	Covers the material receipt, preparation, reaction, bulk transfer and storage, as well as equipment cleaning, and associated maintenance activities in the Process Categories listed above.
<i>Section 2</i>	<i>Operational conditions and risk management measures</i>
<i>Section 2.1</i>	<i>Control of worker exposure</i>
Product characteristics	
Physical form of product	Liquid / physically dispersed in a solid matrix at the end of the dry-blend, compounds formulation
Volatility	Low volatility liquid [OC3] / Solid high dustiness [OC6] at the end of the dry-blend, compounds formulation (<i>assumed for the purpose of a worst case exposure assessment</i>)
Concentration of substance in product	Typical concentration 30% Limit the substance content in the mixture to 50% [OC22]
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2].
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	For dry blending and compounding : Operation is carried out at elevated temperature [OC7]: 100-120° ; For plastisol : Assumes activities are at ambient temperature (unless stated differently) [G17]. Assumes a good basic standard of occupational hygiene is implemented [G1].

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<i>Risk Management Measures</i>			
<i>Identifier*</i>	<i>Contributing Scenarios</i>	<i>Process Categories</i>	<i>Risk Management Measures</i>
ES2-W1	Closed continuous process, Indoors	1	Low volatility liquid [OC3]. Handle substance within a closed system [E47]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES2-W2	Closed continuous process, Indoors	1	Solid, high dustiness [OC6]. Handle substance within a closed system [E47]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES2-W3	General exposures (closed systems); With sample collection; Indoors.	2	Low volatility liquid [OC3]. Handle substance within a closed system [E47]. Sample via a closed loop or other system to avoid exposure [E8]. Avoid carrying out operation for more than 1 hour [OC11]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES2-W4	General exposures (closed systems); With sample collection; Indoors, with LEV present.	2	Low volatility liquid [OC3]. Handle substance within a predominantly closed system provided with extract ventilation [E49]. Avoid carrying out operation for more than 1 hour [OC11]. Sample via a closed loop or other system to avoid exposure [E8]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16]
ES2-W5	General exposures (closed systems); With sample collection; Indoors	2	Solid, high dustiness [OC6]. Aerosol generation due to elevated process temperature [OC25]. Handle substance within a closed system [E47]. Ensure dedicated sample points are provided [E9]. Avoid carrying out operation for more than 1 hour [OC11]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16]
ES2-W6	General exposures	2	Solid, high dustiness [OC6]. Aerosol generation due to elevated process temperature [OC25]. Handle substance

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	(closed systems); With sample collection; Indoors, with LEV present.		within a predominantly closed system provided with extract ventilation [E49]. Avoid carrying out operation for more than 1 hour [OC11]. Ensure dedicated sample points are provided [E9]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16]
ES2-W7	Batch closed process exposures; Indoors	3	Low volatility liquid [OC3]. Handle substance within a closed system [E47]. Sample via a closed loop or other system to avoid exposure [E8]. Avoid carrying out operation for more than 1 hour [OC11]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES2-W8	Batch closed process exposures; indoors with LEV present	3	Low volatility liquid [OC3]. Handle substance within a predominantly closed system provided with extract ventilation [E49]. Avoid carrying out operation for more than 1 hour [OC11]. Sample via a closed loop or other system to avoid exposure [E8]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16]
ES2-W9	Batch closed process exposures; Indoors	3	Solid, high dustiness [OC6]. Aerosol generation due to elevated process temperature [OC25]. Handle substance within a closed system [E47]. Ensure dedicated sample points are provided [E9]. Avoid carrying out operation for more than 1 hour [OC11]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16]
ES2-W10	Batch closed process exposures; indoors with LEV present	3	Solid, high dustiness [OC6]. Aerosol generation due to elevated process temperature [OC25]. Handle substance within a predominantly closed system provided with extract ventilation [E49]. Avoid carrying out operation for more than 1 hour [OC11]. Ensure dedicated sample points are provided [E9]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16]
ES2-W11	Continuous or batch mixing processes for Plastisol	5	Low volatility liquid [OC3]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16]. Handle substance within a predominantly closed system provided with extract ventilation [E49] or: Wear a respirator conforming to

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	formulation of DEHP; indoor,		EN140 with Type A/P2 filter or better {PPE29}
ES2-W12	Drum/batch transfers of DEHP and of liquid formulation; Dedicated facility; Outdoors	8b	Low volatility liquid [OC3]. Ensure operation is undertaken outdoor [OC69]. Avoid carrying out operation for more than 4 hours [OC12]. Transfer via enclosed lines [E52]. Clear transfer lines prior to de-coupling [E39]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES2-W13	Drum/batch transfers of DEHP and of liquid formulation; Dedicated facility; Indoors with LEV	8b	Low volatility liquid [OC3]. Avoid carrying out operation for more than 4 hours [OC12]. Ensure material transfer are under containment or extract ventilation [E66]. Clear transfer lines prior to de-coupling [E39]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES2-W14	Drum/batch transfers of solid formulation; Dedicated facility; Outdoors	8b	Solid, high dustiness [OC6]. Ensure operation is undertaken outdoor [OC69]. Avoid carrying out operation for more than 4 hours [OC12]. Transfer via enclosed lines [E52]. Clear transfer lines prior to de-coupling [E39]. Wear a respirator conforming to EN140 with Type A/P2 filter or better {PPE29}. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES2-W15	Drum/batch transfers of solid formulation; Dedicated facility; Indoors with LEV	8b	Solid, high dustiness [OC6]. Avoid carrying out operation for more than 4 hours [OC12]. Ensure material transfer are under containment or extract ventilation [E66]. Clear transfer lines prior to de-coupling [E39]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].

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<i>measures</i>		
Section 2.2		
Control of environmental exposure		
Identifier*:	ES2-E1	ES2-E2
Contributing scenario	Formulation of DEHP in dry-blend (Process with heating)	Formulation of DEHP in Plastisol (Process without heating)
Environmental Release Category	ERC3	ERC2
Specific ERC	-	
Assessment scenario	n.r.	
Operational Conditions		
Amounts used		
Amounts used in the EU (ktonnes/year)-assumption	230	5
Fraction of substance in end-use products	0.3	
Frequency and duration of use		
Type of release (C= continuous, B=batch)	default	
Emission days (days/year)	default	
Environmental factors not influenced by risk management		
Local freshwater dilution factor	Default	
Local marine water dilution factor	Default	
Other given operational conditions affecting environmental exposure		
Industry category	11 Polymers industry	
Use category	47 Softeners	
Extra details on use category	Polymer processing	
Extra details on use category	Thermoplastics : plastisers	
Emission tables	A2.1 (general table), B2.9 (specific uses)	
Risk Management Measures		
Water		
<i>Discharge to aquatic environment is restricted by the Water Framework Directive[TCS2]</i>		
Soil		
<i>Soil emission controls are not applicable as there is no direct release to soil. [TCR4]</i>		
Air		
<i>ES2-E1: Incinerate, absorb or adsorb vapours stripped from process whenever necessary[A8]</i>		
<i>ES2-E2: Incinerate, absorb or adsorb vapours stripped from process whenever necessary[A8]</i>		
Other environmental control measures additional to above	Dispose of waste cans and containers according to local regulations.	

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

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3. Exposure scenario 3: Processing of formulations containing DEHP as plasticiser through compounding, calendering, spread coating, extrusion, injection moulding into articles and low energy manipulation of the resulting polymers

This scenario covers all the industrial and professional activities associated with processing of formulations containing DEHP as plasticiser through compounding, calendering, spread coating, extrusion, injection moulding and low energy manipulation of the resulting polymers.

3.1. Exposure scenario

<i>Section 1</i>	<i>Exposure Scenario Title</i>
Title	Processing of formulations containing DEHP as plasticiser through compounding, calendering, spread coating, extrusion, injection moulding into articles and low energy manipulation of the resulting polymers
Sector of Use	SU3, SU8, SU10, SU12
Process Category	PROC6, PROC10, PROC13, PROC14, PROC21
Product Category	32
Article Category	nr
Environmental release Category	ERC 5
Specific environmental release category	n/a
Processes, tasks, activities covered	Covers the processing as well as equipment cleaning, and associated maintenance activities in the Process Categories listed above.
<i>Section 2</i>	<i>Operational conditions and risk management measures</i>
<i>Section 2.1</i>	<i>Control of worker exposure</i>
Product characteristics	
Physical form of product	Liquid for Plastisol/ physically dispersed in the solid dry-blend formulation
Volatility	Low volatility liquid [OC3] / Solid high dustiness [OC6] (<i>assumed for the purpose of a worst case exposure assessment</i>)
Concentration of substance in product	Typical concentration 30% Limit the substance content in the mixture to 50% [OC22]
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2].
Human factors not influenced by risk	None identified for this scenario.

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management			
Other Operational Conditions affecting worker exposure		Assumes activities are at ambient temperature (unless stated differently) [G17]. Assumes a good basic standard of occupational hygiene is implemented [G1]. Assumes Industrial (unless stated differently) [G26]	
Risk Management Measures			
Identifier*	Contributing Scenarios	Process Categories	Risk Management Measures
ES3-W1	Calendering operations with liquid formulations, Indoors with LEV	6	Low volatility liquid [OC3]. Aerosol generation due to elevated process temperature [OC25]. Carry out in a vented booth or extracted enclosure [E57]. Avoid carrying out operation for more than 4 hours [OC11]. Wear chemically resistant gloves (tested to EN374) in combination with basic employee training [PPE16]
ES3-W2	Calendering operations with liquid formulations, Indoors	6	Low volatility liquid [OC3]. Aerosol generation due to elevated process temperature [OC25]. Avoid carrying out operation for more than 4 hours [OC11]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with basic employee training [PPE16]
ES3-W3	Calendering operations with dry-blends, Indoors with LEV	6	Solid, high dustiness [OC6]. Aerosol generation due to elevated process temperature [OC25]. Carry out in a vented booth or extracted enclosure [E57]. Avoid carrying out operation for more than 4 hours [OC11]. Wear chemically resistant gloves (tested to EN374) in combination with basic employee training [PPE16]
ES3-W4	Calendering operations with dry-blends, Indoors	6	Solid, high dustiness [OC6]. Aerosol generation due to elevated process temperature [OC25]. Avoid carrying out operation for more than 4 hours [OC11]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with basic employee training [PPE16]
ES3-W5	Roller or brushing applications, with liquid	10	Low volatility liquid [OC3]. Aerosol generation due to elevated process temperature [OC25]. Carry out in a vented booth or extracted enclosure [E57]. Wear a respirator conforming to EN140 with Type A/P2 filter or

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	formulations, Indoors with LEV		better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES3-W6	Dipping, pouring, spread coating applications with liquid formulations, Indoors	13	Low volatility liquid [OC3]. Aerosol generation due to elevated process temperature [OC25]. Limit the substance content in the article to 25% [OC18]. Carry out in a vented booth or extracted enclosure [E57]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES3-W7	Extrusion, tableting, compression, pelletisation operations with liquid formulation, Indoors	14	Low volatility liquid [OC3]. Aerosol generation due to elevated process temperature [OC25]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with basic employee training [PPE16]
ES3-W8	Extrusion, tableting, compression, pelletisation operations with liquid formulation, Indoors with LEV	14	Low volatility liquid [OC3]. Aerosol generation due to elevated process temperature [OC25]. Carry out in a vented booth or extracted enclosure [E57]. Wear chemically resistant gloves (tested to EN374) in combination with basic employee training [PPE16]
ES3-W9	Extrusion, tableting, compression, pelletisation operations with dry-blends, Indoors	14	Solid, high dustiness [OC6]. Aerosol generation due to elevated process temperature [OC25]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES3-W10	Extrusion, tableting, compression, pelletisation operations with dry-blends,	14	Solid, high dustiness [OC6]. Aerosol generation due to elevated process temperature [OC25]. Carry out in a vented booth or extracted enclosure [E57]. Wear chemically resistant gloves (tested to EN374) in combination with basic employee training [PPE16]

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	Indoors with LEV		
ES3-W11	Low energy manipulation of articles such as cutting, welding, glueing, Indoor with LEV	21	Solid, high dustiness [OC6]. Carry out in a vented booth or extracted enclosure [E57]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES3-W12	Low energy manipulation of articles such as cutting, welding, glueing, Indoors	21	Solid, high dustiness [OC6]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].
ES3-W13	Low energy manipulation of articles such as cutting, welding, glueing, Indoors with LEV	21	Professional [G27]. Solid, high dustiness [OC6]. Carry out in a vented booth or extracted enclosure [E57]. Wear suitable gloves (tested to EN374), coverall and eye protection [PPE23].
ES3-W14	Low energy manipulation of articles such as cutting, welding, glueing, Indoors	21	Professional [G27]. Solid, high dustiness [OC6]. Wear a respirator conforming to EN140 with Type A/P2 filter or better [PPE29]. Wear suitable gloves (tested to EN374), coverall and eye protection [PPE23].
ES3-W15	Low energy manipulation of articles such as cutting, welding, glueing,	21	Professional [G27]. Solid, high dustiness [OC6]. Avoid carrying out operation for more than 1 hour [OC11]. Wear suitable gloves (tested to EN374), coverall and eye protection [PPE23].

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	Indoors		
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Section 2	<i>Operational conditions and risk management measures</i>				
Section 2.2	<i>Control of environmental exposure</i>				
Identifier*:	ES3-E1	ES3-E2	ES3-E3	ES3-E4	ES3-E5
Contributing scenarios					
ES3-E1	Mixing, Compounding, Extrusion, Injection moulding				
ES3-E2	Calendering				
ES3-E3	Spread coating				
ES3-E4	Processing of Plastisol (Dip/slush moulding, Rotational moulding)				
ES3-E5	Low energy manipulation of polymers				
Environmental Release Category	ERC5				
Specific ERC	-				
Assessment scenario	n.r.				
Operational Conditions					
Amounts used					
Amounts used in the EU (ktonnes/year)	120	37	38	5	nr
Fraction of EU tonnage for application	60%	18.5%	19%	2.5%	nr
Fraction of main source to local environment	0.01	0.05	0.01	0.1	nr
Fraction of substance in end-use products	0.3				
Frequency and duration of use					
Type of release (C= continuous, B=batch)					
Emission days (days/year)	300 (default)				
Daily amount in 2009 (tonnes per day)					
Environmental factors not influenced by risk management					
Environmental factors not influenced by risk management					
Release fraction to waste water	1.50E-5	2.50E-5	2.50E-5	5.00E-5	nr
Release fraction in air	1.50E-5	2.50E-4	2.50E-4	5.00E-5	nr
Release fraction in soil	0	0	0	0	0
Other given operational conditions affecting environmental exposure					
Industry category	11 Polymers industry				
Use category	47 Softener				
Emission tables	A3.11 (general table), B3.9 (general table)				
Local freshwater dilution factor	Default				
Local marine water dilution factor	Default				

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Other given operational conditions affecting environmental exposure	Handle substance within a closed system [E47]. Sample via a closed loop or other system to avoid exposure [E8]. Collect all waste waters and spillages for treatment by WWTP or other suitable system
Risk Management Measures	
Water	
<i>Wastewater emission controls are not applicable as there is no direct release to wastewater.[TCR3] – dry processes</i> However, in case of emission of DEHP contaminated waste water: <i>Discharge to aquatic environment is restricted by the Water Framework Directive[TCS2]</i>	
Soil	
<i>Soil emission controls are not applicable as there is no direct release to soil. [TCR4]</i>	
Air	
<i>ES3-E1, ES3-E2, ES3-E3, ES3-E4: Incinerate, absorb or adsorb vapours stripped from process whenever necessary[A8]</i>	
Other environmental control measures additional to above	Dispose of waste cans and containers according to local regulations.

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

4. Exposure scenario 4: Service life of DEHP used as plasticiser in articles

This scenario covers the activities associated with the service life of DEHP as plasticiser in articles excluding toys and articles for food contact.

4.1. Exposure scenario

<i>Section 1</i>	<i>Exposure Scenario Title</i>
Title	Service life of DEHP used as plasticiser in articles
Sector of Use	SU21
Process Category	
Product Category	32
Article Category	AC5, 10, 13 excluding toys and articles for food contact
Environmental release Category	ERC10a, 11a
Specific	n/a

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environmental release category	
Processes, tasks, activities covered	Covers the service life of articles containing DEHP as plasticiser
Section 2	Operational conditions and risk management measures
Section 2.1	Control of consumer exposure
Product characteristics	
Physical form of product	Physically dispersed in the plastic matrix
Volatility	Very low volatility
Concentration of substance in product	Typical concentration 30%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers all types of exposure
Human factors not influenced by risk management	None identified for this scenario.

<i>Identifier*</i>	<i>Contributing Scenarios</i>	<i>Risk Management Measures</i>
ES4-C1	Service life of plastic articles containing DEHP as plasticiser	Follow the use instructions

Section 2.2	Control of environmental exposure	
Identifier: ES4-E1		
Contributing scenario ES6-ENV1	Environmental exposure during service life indoor use	
Environmental Release Category	ERC11a	
Specific ERC	n.r.	
Assessment scenario	n.r.	
Identifier: ES4-E2		
Contributing scenario ES6-ENV1	Environmental exposure during service life outdoor use	
Environmental Release Category	ERC10a	
Specific ERC	n.r.	
Assessment scenario	n.r.	
Operational Conditions		
Amounts used		

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Amounts used in the EU (ktonnes/year)	144 (ES4-E1) ; 56 (ES4-E2)	
Fraction of EU tonnage used in region	0.72 (ES4-E1) ; 0.28 (ES4-E2)	
Fraction of main local source	5.5E-07	
Fraction of substance in end-use products	0.3	
Frequency and duration of use		
Type of release (C= continuous, B=batch)	C	
Emission days (days/year)	365	
Environmental factors not influenced by risk management		
Flow rate of receiving surface water (m ³ /d)	Default value of 18,000 m ³ /d*	
Other given operational conditions affecting environmental exposure		
Technology or process techniques determining the initial release of substance	Wastewater	Cleaning of the articles with water
Usage of articles	Indoor for ES4-E1 ; Outdoor for ES4-E2	
Conditions and measures related to municipal sewage treatment plant		
Size of municipal sewage system/treatment plant (m ³ /d)	Default value of 2,000 m ³ /d**	
Conditions and measures related to disposal of articles at end of service life		
Type of waste treatment	Medical devices	Incineration
	Other articles	Landfill or incineration
Efficacy of treatment	Incineration	100%
Other given operational conditions affecting environmental exposure		Dispose of articles according to local regulations

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5. Exposure scenario 5: Service life of DEHP as plasticiser in medical devices

Medical devices are products used for medical purposes on patients, indidiagnosis, therapy and surgery, as defined in EU Directive 93/42/EEC. A number of medical devices may be made of PVC plastics flexible through the use of platicisers such as DEHP. DEHP can migrate from medical devices, hence resulting in the exposure of patients to DEHP. It appears that in most of the cases, the highest exposure of patients to DEHP result from the contact of the plasticized PVC with “lipidic fluids”. As a result two contributing scenarios are proposed: one to adress the low exposure medical devices and clinical procedures and onr for the high exposure.

5.1. Exposure scenario

<i>Section 1</i>	<i>Exposure Scenario Title</i>
Title	Service life of DEHP used as plasticiser in medical devices
Sector of Use	SU20, SU21
Process Category	Not relevant
Product Category	32
Article Category	AC13, medical devices
Environmental release Category	ERC11a
Specific environmental release category	n/a
Processes, tasks, activities covered	Covers the service life of medical devices and medical procedures involving platics containing DEHP as plasticiser.
<i>Section 2</i>	<i>Operational conditions and risk management measures</i>
<i>Section 2.1</i>	<i>Control of patient exposure</i>
Product characteristics	
Physical form of product	Physically dispersed in the plastic matrix
Volatility	Very low volatility
Concentration of substance in product	Typical concentration 30%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers exposures as prescribed in the clinical procedures.

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Human factors not influenced by risk management	None identified for this scenario.
Other factors influencing the risk assessment	lipophilicity of the fluid that comes into contact with the medical devices, the PVC surface size, the temperature, the flow rate, the contact time, the bodyweight of the patient

<i>Identifier*</i>	<i>Contributing Scenarios</i>	<i>Risk Management Measures</i>
ES5-C1	Clinical procedures and medical devices leading to low levels of exposure	Conduct a risk/benefit analysis for each individual medical device and each medical procedure according to the essential requirements of Directive 93/42/EEC. Label the presence of DEHP in the medical devices according to the requirements of Directive 2007/47/EC
ES5-C2	Clinical procedures leading to potentially high levels of exposure. The following situations were identified in particular: -exchange transfusion in neonates - ECMO in neonates - TPN in neonates - Multiple procedures in sick neonates - Haemodialysis in peripubertal males - Haemodialysis in pregnant or lactating women - Enteral nutrition in neonates and adults - Heart transplantation or coronary artery bypass graft surgery - Massive infusion of blood into trauma patient - transfusion in adult undergoing ECMO	Conduct a risk/benefit analysis for each individual medical device and each medical procedure according to the essential requirements of Directive 93/42/EEC. ¹ Label the presence of DEHP in the medical devices according to the requirements of Directive 2007/47/EC. ¹ As an example of risk minimising approach: <ul style="list-style-type: none"> - identify if alternatives exist - avoid contact with lipidic fluids - minimise duration of contact with lipidic fluids

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6. Exposure scenario 6: Use as laboratory reagent

6.1. Exposure scenario

<i>Section 1</i>	<i>Exposure Scenario Title</i>
Title	Use as laboratory chemical
Sector of Use	SU8, 9, 24
Process Category	PROC15
Product Category	PC21
Article Category	n/a
Environmental release Category	Adressed under ERC1 in 9.1
Specific environmental release category	n/a
Processes, tasks, activities covered	Covers the use of the substance as laboratory chemical
<i>Section 2</i>	<i>Operational conditions and risk management measures</i>
<i>Section 2.1</i>	<i>Control of worker exposure</i>
Product characteristics	
Physical form of product	Liquid
Volatility	Very low volatility
Concentration of substance in product	Up to 100%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2].
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes activities are at ambient temperature (unless stated differently) [G17]. Assumes a good basic standard of occupational hygiene is implemented [G1].

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<i>Risk Management Measures</i>			
<i>Identifier*</i>	<i>Contributing Scenarios</i>	<i>Process Categories</i>	<i>Risk Management Measures</i>
ES5-W1	Laboratory activities; Indoors, with LEV present.	15	Handle in a fume cupboard or under extract ventilation [E83]. Avoid carrying out operation for more than 1 hour [OC11]; Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training [PPE16].

The residues following use in small scale analytical laboratories are incinerated together with residues from manufacturing at production sites. Thus, this use (PROC15) is linked with ERC1 (manufacture and distribution) and therefore no further environmental assessment is required.