

Scheda di dati di sicurezza ai sensi del regolamento 1907/2006/CE, Articolo 31

Data di compilazione: 24.01.2011

Versione: 3

Revisione: 04.01.2011

* 1 Identificazione della sostanza o della miscela e della società/impresa

- **Identificatore del prodotto**
- **Denominazione commerciale:** **Phthalic Anhydride (PA) solid**
(with no more than 0,05% maleic anhydride)
- **Numero CAS:**
285-44-9
- **Numero EINECS:**
201-607-5
- **Numero indice:**
607-009-00-4
- **Numero di registrazione** 01-2119457017-41-0020
- **Usi pertinenti identificati della sostanza o miscela e usi sconsigliati**
Nessuno degli usi identificati è sconsigliato.
Vedi appendice
- **Utilizzazione della Sostanza / del Preparato**
Materie prime per vernice
Resina al poliestere
Plasticante
- **Informazioni sul fornitore della scheda di dati di sicurezza**
- **Produttore/fornitore:**
Penpet Petrochemical Trading GmbH
Merkurring 105
22143 Hamburg
Germany
Tel: +49 40 675 799 0
Fax: +49 40 675 799 99 / 88
- **Indirizzo e-mail della persona competente:** angelika.torges@kft.de
- **Informazioni fornite da:** Vedi produttore/fornitore
- **Numero telefonico di emergenza:**
Centro antiveleni,
Ospedale Niguarda "Ca Granda"
Piazza Ospedale Maggiore 3
20162 Milano

Tel.: (+39)-02-66 10 10 29

* 2 Identificazione dei pericoli

- **Classificazione della sostanza o della miscela**
- **Classificazione secondo il regolamento (CE) n. 1272/2008**



GHS08 pericolo per la salute

Resp. Sens. 1 H334 Può provocare sintomi allergici o asmatici o difficoltà respiratorie se inalato.



GHS05 corrosione

Eye Dam. 1 H318 Provoca gravi lesioni oculari.



GHS07

Acute Tox. 4 H302 Nocivo se ingerito.

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Skin Irrit. 2 H315 Provoca irritazione cutanea.
Skin Sens. 1 H317 Può provocare una reazione allergica cutanea.
STOT SE 3 H335 Può irritare le vie respiratorie.

• Classificazione secondo la direttiva 67/548/CEE o direttiva 1999/45/CE Xn; Nocivo

R22: Nocivo per ingestione.

 Xn; Sensibilizzante

R42/43: Può provocare sensibilizzazione per inalazione e contatto con la pelle.

 Xi; Irritante

R37/38-41: Irritante per le vie respiratorie e la pelle. Rischio di gravi lesioni oculari.

• Sistema di classificazione:

La classificazione corrisponde alle attuali liste della CEE, è tuttavia integrata da dati raccolti da bibliografia specifica e da dati forniti dall'impresa.

• Elementi dell'etichetta**• Etichettatura secondo il regolamento (CE) n. 1272/2008**

La sostanza è classificata ed etichettata conformemente al regolamento CLP.

• Pittogrammi di pericolo

GHS05 GHS07 GHS08

• Avvertenza Pericolo**• Indicazioni di pericolo**

H302 Nocivo se ingerito.
H315 Provoca irritazione cutanea.
H318 Provoca gravi lesioni oculari.
H334 Può provocare sintomi allergici o asmatici o difficoltà respiratorie se inalato.
H317 Può provocare una reazione allergica cutanea.
H335 Può irritare le vie respiratorie.

• Consigli di prudenza

P280 Indossare guanti di protezione/Proteggere gli occhi.
P264 Lavare accuratamente dopo l'uso.
P305+P351+P338 IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare.
P342+P311 In caso di sintomi respiratori: contattare un CENTRO ANTIVELENI o un medico.
P304+P341 IN CASO DI INALAZIONE: se la respirazione è difficile, trasportare l'infortunato all'aria aperta e mantenerlo a riposo in posizione che favorisca la respirazione.
P333+P313 In caso di irritazione o eruzione della pelle: consultare un medico.
P501 Smaltire il prodotto/recipiente in conformità con le disposizioni locali / regionali / nazionali / internazionali.

• Altri pericoli**• Risultati della valutazione PBT e vPvB**

• **PBT:** Le proprietà della sostanza non corrispondono ai criteri di prova.
• **vPvB:** Le proprietà della sostanza non corrispondono ai criteri di prova.

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3 Composizione/informazioni sugli ingredienti

- **Caratteristiche chimiche: Sostanze**
- **Numero CAS**
285-44-9 anidride ftalica
- **Numero/i di identificazione**
- **Numero EINECS:** 201-607-5
- **Numero indice:** 607-009-00-4

* 4 Misure di primo soccorso

- **Descrizione delle misure di primo soccorso**
- **Indicazioni generali:**
Togliersi immediatamente gli abiti contaminati dal prodotto.
I sintomi di avvelenamento possono comparire dopo molte ore, per tale motivo è necessaria la sorveglianza di un medico nelle 48 ore successive all'incidente.
- **Inalazione:**
Portare il soggetto in zona molto ben areata e per sicurezza consultare un medico.
Se il soggetto è svenuto provvedere a tenerlo durante il trasporto in posizione stabile su un fianco.
- **Contatto con la pelle:**
Lavare accuratamente con un detergente delicato e con abbondante acqua le parti colpite di modo che non permangano residui di sostanza sulla pelle.
In caso di irritazioni cutanee persistenti consultare il medico.
- **Contatto con gli occhi**
Proteggere l'occhio non colpito.
Lavare con acqua gli occhi con palpebre aperte per 10 - 15 min.
Trasporto immediato da un oculista o in clinica oculistica.
- **Ingestione:**
Risciacquare la bocca e bere molta acqua.
Non fare mai ingerire liquidi se il soggetto si trova in stato di incoscienza.
Non provocare il vomito, chiamare subito il medico.
Nel caso che la persona vomiti spontaneamente:
In caso di vomito tenere la testa in basso per evitare l'aspirazione
- **Indicazioni per il medico:**
- **Principali sintomi ed effetti, sia acuti che ritardati**
Effetti d'irritazione locale
Tosse
Disturbi asmatici
- **Indicazione della eventuale necessità di consultare immediatamente un medico e di trattamenti speciali**
Trattamento sintomatico
(decontaminazione, funzione vitale)
In caso di irritazione polmonare effettuare il primo trattamento con aerosol al desametasone.

* 5 Misure antincendio

- **Mezzi di estinzione**
- **Mezzi di estinzione idonei:**
CO₂, polvere o acqua nebulizzata. Estinguere gli incendi di grosse dimensioni con acqua nebulizzata o con schiuma resistente all'alcool.
Adottare provvedimenti antiincendio nei dintorni della zona colpita.
- **Mezzi di estinzione inadatti per motivi di sicurezza:** Getti d'acqua.
- **Pericoli speciali derivanti dalla sostanza o dalla miscela**
In caso di incendio si possono liberare:

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Monossido di carbonio (CO)

Gas/vapori irritanti

- **Raccomandazioni per gli addetti all'estinzione degli incendi**

- **Mezzi protettivi specifici:**

Portare un respiratore ad alimentazione autonoma.

Indossare tute protettive integrali.

- **Altre indicazioni**

Smaltire come previsto dalle norme di legge i residui dell'incendio e l'acqua contaminata usata per lo spegnimento.

Raccogliere l'acqua contaminata usata per lo spegnimento, non convogliarla assolutamente nel sistema fognario.

* 6 Misure in caso di rilascio accidentale

- **Precauzioni personali, dispositivi di protezione e procedure in caso di emergenza**

Evitare la formazione di polvere

Garantire una ventilazione sufficiente.



Indossare equipaggiamento protettivo. Allontanare le persone non equipaggiate.

In caso di vapori/polvere/aerosol adottare protezioni respiratorie.

- **Precauzioni ambientali:**

Impedire l'entrata del prodotto nelle fognature o nei corpi d'acqua.

Impedire l'infiltrazione nel sottosuolo/terreno.

- **Metodi e materiali per il contenimento e per la bonifica:**

Raccogliere meccanicamente.

Evitare assolutamente la formazione di polvere. Aspirare con un aspirapolvere industriale controllato ed omologato.

Provvedere ad una sufficiente areazione.

Lasciare solidificare e prelevare meccanicamente il prodotto fuso.

Effettuare il recupero o lo smaltimento in appositi serbatoi.

Smaltimento del materiale contaminato conformemente al punto 13

- **Riferimento ad altre sezioni**

Per informazioni relative ad un manipolazione sicura, vedere capitolo 7.

Per informazioni relative all'equipaggiamento protettivo ad uso personale vedere Capitolo 8.

Per informazioni relative allo smaltimento vedere Capitolo 13.

* 7 Manipolazione e immagazzinamento

- **Manipolazione:**

- **Precauzioni per la manipolazione sicura**

Accurata ventilazione/aspirazione nei luoghi di lavoro.

Evitare la formazione di polvere.

Eliminare regolarmente la polvere, di cui non è possibile evitare la formazione.

Non respirare le polveri.

Evitare il contatto con pelle e occhi

Manipolare il prodotto fuso solo all'interno di sistemi chiusi.

- **Indicazioni in caso di incendio ed esplosione:**

Debbono essere osservate le regole generali di protezione antincendio aziendale.



Tenere lontano da fonti di calore, non fumare.

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- **Condizioni per l'immagazzinamento sicuro, comprese eventuali incompatibilità**
- **Stoccaggio:**
- **Requisiti dei magazzini e dei recipienti:** Conservare chiuso ermeticamente in luogo fresco, asciutto e sufficientemente ventilato.
- **Indicazioni sullo stoccaggio misto:**
Non conservare a contatto con alimenti.
Conservare separatamente dai mangimi
- **Ulteriori indicazioni relative alle condizioni di immagazzinamento:**
Mantenere i recipienti ermeticamente chiusi.
Proteggere da umidità e acqua.
- **Classe di stoccaggio:** 11 Sostanze solide infiammabili

* 8 Controllo dell'esposizione/protezione individuale

- **Ulteriori indicazioni sulla struttura di impianti tecnici:** Nessun dato ulteriore, vedere punto 7
- **Parametri di controllo**
- **Componenti i cui valori limite devono essere tenuti sotto controllo negli ambienti di lavoro** viene meno
- **DNEL**
Abbreviazioni:
In = Industrial
Prof = Professional
Cons = Consumer

LLE = Long term, local effects
LSE = Long term, systemic effects
SLE = Short term, local effects
SSE = Short term, systemic effects

Orale DNEL/Cons/LSE 5 mg/kg bw/day (Human)
 DNEL/In/LSE 10 mg/kg bw/day (Human)

Cutaneo DNEL/Cons/LSE 5 mg/kg bw/day (Human)
 DNEL/In/LSE 10 mg/kg bw/day (Human)

Per inalazione DNEL/Cons/LSE 8,6 mg/m³ (Human)
 DNEL/In/LSE 35,2 mg/m³ (Human)
- **PNEC**
Abbreviazioni
aq = acqua
sed = sediment

PNEC 0,153 mg/kg (soil)
 10 mg/l (sewage treatment plant)

PNEC/Aq 1 mg/l (fresh water)
 5,6 mg/l (intermittent release)
 0,1 mg/l (marine water)

PNEC/sed 0,826 mg/kg (fresh water)
 0,0826 mg/kg (marine water)
- **Controlli dell'esposizione**
- **Mezzi protettivi individuali**
- **Norme generali protettive e di igiene del lavoro:**
Tenere lontano da cibo, bevande e foraggi.
Durante il lavoro è vietato mangiare e bere.
Togliere immediatamente gli abiti contaminati.
Aspirare gli abiti contaminati, non soffiare né spazzolare.
Non inalare polvere/fumo/nebbia.
Evitare assolutamente il contatto con gli occhi e con la pelle.
In seguito a contatto con la sostanza è necessario un lavaggio della pelle.
Installare sul posto di lavoro strutture per il lavaggio.

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In seguito a contatto degli occhi con la sostanza, praticare un lavaggio.
 Prevedere una stazione per il lavaggio oculare.

• **Maschera protettiva:**

Al superamento del valore limite di presenza nell'aria e in caso di rilascio accidentale della sostanza:



Nelle esposizioni brevi e minime utilizzare la maschera; nelle esposizioni più intense e durature indossare l'autorespiratore.

Apparecchio di filtraggio temporaneo:
 Filtro A/P2.

• **Guanti protettivi:**

Guanti protettivi resistenti alle sostanze chimiche (EN 374)

Prima di ogni nuovo utilizzo dei guanti è da controllare l'impermeabilità.

Il materiale dei guanti deve essere impermeabile e stabile contro il prodotto/ la sostanza/ la formulazione.

Scelta del materiale dei guanti in considerazione dei tempi di passaggio, dei tassi di permeazione e della degradazione.

È consigliata a scopo preventivo la protezione della pelle utilizzando agenti di protezione dell'epidermide.

Dopo l'impiego dei guanti adoperare del detergente e della crema curativa per la pelle.

• **Materiale dei guanti**

La scelta dei guanti adatti non dipende soltanto dal materiale bensì anche da altre caratteristiche di qualità variabili da un produttore a un altro.

Per le sostanze solide non dissolte occorre prendere in considerazione:

Gomma nitrilica

Gomma butilica

Gomma polycloroprene

Fluoro-caucciù

• **Tempo di permeazione del materiale dei guanti**

Richiedere dal fornitore dei guanti il tempo di passaggio preciso il quale deve essere rispettato.

• **Occhiali protettivi:** Occhiali protettivi a tenuta.

• **Tuta protettiva:**

Tuta protettiva.

La scelta degli indumenti protettivi deve essere fatta a seconda del tipo di attività da svolgersi e del potenziale di pericolosità ad essa legato.

*** 9 Proprietà fisiche e chimiche**

• **Informazioni sulle proprietà fisiche e chimiche fondamentali**

• **Indicazioni generali**

• **Aspetto:**

Forma: cristallino

Colore: incolore

• **Odore:** aromatico

• **Cambiamento di stato**

Temperatura di fusione/ambito di fusione: 131,6°C

Temperatura di ebollizione/ambito di ebollizione: 284,5°C

• **Punto di infiammabilità:** 152°C

• **Temperatura di accensione:** 580°C

• **Pericolo di esplosione:** Il prodotto non è esplosivo; è tuttavia possibile il formarsi di miscele di polvere/aria esplosive.

• **Limiti di infiammabilità:**

inferiore: 1,7 Vol %

superiore: 10,5 Vol %

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· Tensione di vapore a 20°C:	0,0006 hPa
· Densità a 20°C:	1,527 g/cm ³
· Solubilità in/Miscibilità con Acqua:	Idrolizzato ad acido ftalico
· Coefficiente di distribuzione (n-Octanol/acqua):	1,6 log POW

10 Stabilità e reattività

- **Reattività**
- **Stabilità chimica**
- **Decomposizione termica/ condizioni da evitare:**
Il prodotto non si decompone se manipolato e immagazzinato secondo le norme.
Non riscaldare onde evitare decomposizione termica.
- **Possibilità di reazioni pericolose**
La concentrazione di polvere fine in presenza di aria può determinare il pericolo di esplosione pulverulenta.
Reazione con le sostanze sotto nominate.
- **Materiali incompatibili:**
Acido nitrico
Metalli
Acqua ed umidità
- **Prodotti di decomposizione pericolosi:**
Non si formano prodotti di decomposizione pericolosi se sono osservate le prescrizioni per l'immagazzinamento e l'uso.

*11 Informazioni tossicologiche

- **Informazioni sugli effetti tossicologici**
- **Tossicità acuta:**
- **Valori LD/LC50 rilevanti per la classificazione:**

Orale	LD ₅₀	1530 mg/kg (rat)
Per inalazione	LC ₅₀ /4 h	> 2,14 mg/l (rat) analytical
- **Irritabilità primaria:**
- **Sulla pelle:**
Irrita la pelle e le mucose.
Le polveri dei prodotti sono irritanti per le prime vie respiratorie
- **Sugli occhi:** Forte irritazione con rischio di gravi lesioni oculari
- **Sensibilizzazione:**
Può provocare sensibilizzazione se inalato
Può provocare sensibilizzazione a contatto con la pelle.
- **Ulteriori dati (relativi alla tossicità sperimentale):**
Ames-Test: negativo
Sister Chromatid Exchange in Chinese Hamster Ovary Cells (sister chromatid exchange) OECD 479: negativo
- **Azioni cancerogene, mutagene e tossiche per il ciclo riproduttivo:**
Nessuna indicazione di azione cancerogena Studio di somministrazione orale con ratti per 105 settimane. NOAEL: 1000 mg/kg di peso corporeo/giorno

Nell'ambito di questo studio non sono emersi nemmeno effetti tossici-riproduttivi sugli organi riproduttivi.

Notoriamente l'anidride ftalica si idrolizza ad acido ftalico al contatto con l'acqua. Probabilmente si deve presumere che una reazione simile si verificherà in sistemi biologici.

Conformemente i risultati sono stati impiegati per la tossicità sullo sviluppo dell'acido ftalico.

Al riguardo sono disponibili i seguenti risultati:

NOAEL = 1000 mg/kg di peso corporeo per la tossicità materna

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NOAEL = 1700 mg/kg di peso corporeo/giorno teratogenicità

· Tossicità a dose ripetuta

Orale NOAEL 500 mg/kg/day (rat)

***12 Informazioni ecologiche**
· Tossicità
· Tossicità acquatica:

EC ₅₀ (statico)	> 1000 mg/l (activated sludge) (ISO 8192)
	3h
	213 mg/l (pseudomonas putida) (ISO 10712)
	16h
EC ₅₀ /48h (statico)	> 640 mg/l (daphnia magna)
	fresh-water
EC ₅₀ /72h	68 mg/l (Pseudokirchneriella subcapitata) (OECD 201)
LC ₅₀	560 mg/l (danio rerio) (OECD 210)
	7d, freshwater, semi-static (nominal)
NOEC	10 mg/l (Onchorhynchus mykiss) (OECD 210)
	60d, fresh-water, semi-static (nominal)
NOEC/21d	16 mg/l (daphnia magna) (OECD 211)
	freshwater, (nominal)
NOEC/72 h	≥ 100 mg/l (des)
	32 mg/l (Pseudokirchneriella subcapitata)

· Persistenza e degradabilità
· Ulteriori indicazioni:

Il prodotto è facilmente biodegradabile.

Biodegradabilità:

85,2 % in 28 giorni

· Comportamento in compartimenti ecologici:
· Potenziale di bioaccumulo

In base al coefficiente di distribuzione n-Octanol/acqua non è da aspettarsi un'accumulazione notevole in organismi.

· BCF: 3,4 (calcolato)
· Coefficiente di adsorbimento Koc:

Podzol: 31

Alfisol (agricultural soil): 2

Sediment (Lake Constance): 2

(Read across - acido ftalico)

· Ulteriori indicazioni in materia ambientale:
· Ulteriori indicazioni:

Pericolosità per le acque classe 1 (D) (Classif. secondo le liste): poco pericoloso

Non immettere nelle acque freatiche, nei corsi d'acqua o nelle fognature non diluito o in grandi quantità.

Rischio di inquinamento acque potabili in caso di penetrazione di elevate quantità nel sottosuolo o nelle acque

· Risultati della valutazione PBT e vPvB
· PBT: Le proprietà della sostanza non corrispondono ai criteri di prova.

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13 Considerazioni sullo smaltimento

- **Metodi di trattamento dei rifiuti**
- **Consigli:**



Non smaltire il prodotto insieme ai rifiuti domestici. Non immettere nelle fognature

Da destinarsi a regolare smaltimento nel rispetto delle disposizioni sul riciclaggio/smaltimento dei rifiuti. La classificazione dei rifiuti deve avvenire in modo specifico a seconda della provenienza in base al Catalogo Europeo dei Rifiuti (Decisione 2000/532/CE nella versione attuale).

- -
- 07 07 99 rifiuti non specificati altrimenti

- **Imballaggi non puliti:**
- **Consigli:** Smaltimento in conformità con le disposizioni amministrative.

*14 Informazioni sul trasporto

- **Trasporto stradale/ferroviario ADR/RID (oltre confine):**
- **Classe ADR/RID-GGVSEB:** Merce non pericolosa ai sensi del regolamento.
- **Osservazioni:** L'anidride ftalica allo stato solido e l'anidride tetraidroftalica con al massimo 0,05% di anidride maleica non sono soggette alle disposizioni del regolamento ADR/RID. L'anidride ftalica con al massimo 0,05% di anidride maleica che viene spedita o trasportata riscaldata allo stato fuso oltre il proprio punto di infiammabilità deve essere attribuita al numero UN 3256.
- **Trasporto marittimo IMDG:**
- **Classe IMDG:** Merce non pericolosa ai sensi del regolamento
- **Osservazioni:** Phthalic anhydride in the solid state and tetrahydrophthalic anhydride, with no more than 0,05% maleic anhydride, are not subject to these regulations. Phthalic anhydride molten at a temperature above its flashpoint, with not more than 0,05% maleic anhydride should be classified under UN 3256.
- **Trasporto aereo ICAO-TI e IATA-DGR:**
- **Classe ICAO/IATA:** Merce non pericolosa ai sensi del regolamento.
- **Osservazioni:** Phthalic anhydride in the solid state and tetrahydrophthalic anhydrides, with 0,05% or less maleic anhydride, are not subject to these Regulations. Phthalic anhydride molten at a temperature above its flashpoint, with 0,05% or less maleic anhydride must be classified under UN 3256.
- **Precauzioni speciali per gli utilizzatori** Non applicabile.

*15 Informazioni sulla regolamentazione

- **Norme e legislazione su salute, sicurezza e ambiente specifiche per la sostanza o la miscela**
- **Disposizioni nazionali:**
- **Indicazioni relative alla limitazione delle attività lavorative:**
 - Osservare le limitazioni di impiego per bambini.
 - Osservare le limitazioni di impiego per donne in gravidanza o in allattamento.
- **Classe di pericolosità per le acque:** Pericolosità per le acque classe 1 (WGK1) (Classif. secondo le liste): poco pericoloso
- **Valutazione della sicurezza chimica:**
 - Una valutazione della sicurezza chimica è stata effettuata.
 - Vedi appendice

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Una valutazione della sicurezza chimica non è stata effettuata.

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16 Altre informazioni

I dati sono riportati sulla base delle nostre conoscenze attuali, non rappresentano tuttavia alcuna garanzia delle caratteristiche del prodotto e non motivano alcun rapporto giuridico contrattuale.

• **Motivi di cambiamento**

GHS Regolamento (CE) n. 1272/2008

Regolamento (CE) n. 453/2010

Informazioni ecologiche

Dati sulla tossicità

Integrazione dei dati caratteristici

Numero de registrazione

Revisione generale

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• **Scheda rilasciata da:**

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• **Abbreviazioni e acronimi:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

• **Fonti**

ESIS (European existing Substances Information System)

Relazione sulla sicurezza chimica

• *** Dati modificati rispetto alla versione precedente**

I capitoli contrassegnati con * presentano delle modifiche rispetto alla versione precedente

9 EXPOSURE ASSESSMENT

Exposure scenarios to investigate the exposure of workers and the environment to phthalic anhydride during its life cycle have been established in this section. The exposure scenarios have been chosen in order to provide as much coverage as possible over the substance life cycle.

For the environmental assessment EUSES 2.1 has been used to demonstrate the predicted environmental levels of phthalic anhydride using the ERC defaults (in the first tier) with more representative inputs being used in tier 2. In cases where the tier 1 assessments were not sufficient to demonstrate safe use only the second tier assessment is presented in order to prevent multiple tiers of superseded data being present in section 9.

For worker exposure respiratory sensitization has been identified as the key toxicological concern for phthalic anhydride and so a qualitative assessment of sensitization has been presented (in addition to generation of worker exposure levels and comparison to the REACH derived DNELs) in accordance with REACH guidance.

Based on the current data package available for skin sensitisation and the reliability of the studies, it is not deemed possible to derive a DNEL for sensitisation. Therefore, it is not possible to compare the estimated exposure obtained for each ES in Section 9 below using ECETOC with a threshold for induction or elicitation. However, the strict conditions of production and uses are considered sufficient to avoid any exposure. Furthermore, medical monitoring of the workers is also used as a mean of risk management. Given that it is not possible to derive a sensitization DNEL and carry out a quantitative risk characterisation for sensitization a qualitative assessment has been carried out specifically for the production and uses of phthalic anhydride.

Phthalic anhydride is a known skin and respiratory sensitizer and is assigned the R-phrases R42/43 “may cause sensitisation by inhalation and skin contact”.

The skin sensitising potential of phthalic anhydride was investigated in a number of animal studies such as the guinea pig maximisation test (GMPT) and the local lymph node assay (LLNA). It was also confirmed as a skin sensitizer in occupational studies in humans. An attempt to derive an EC3 from an LLNA test was performed by Van Och (2000) and the EC3 value was estimated to be 0.357% (Van Och, 2000) which is borderline for potency categorisation as extreme ($EC3 \leq 0.2\%$) or strong sensitizer ($0.2\% < EC3 \leq 2\%$) according to Guidance document R.8. The authors (Van Och, 2000) concluded that phthalic anhydride should be regarded as extreme sensitizer. Furthermore, studies in guinea pigs have also shown that phthalic anhydride should be considered as an extreme skin sensitizer.

Although there is no validated test for respiratory sensitisation in animals, an inhalation study was performed on guinea pig exposed to aerosolised phthalic anhydride-guinea pig serum albumin (PA-GPSA) and elicited respiratory reaction. A subgroup of animals did not elicit a response however measurement of antibodies to PA-GPSA showed an increase in specific IgG antibodies. These results are also confirmed by reactions reported in workers exposed to PA such as work-related rhinitis, chronic productive bronchitis, and work associated asthma. Phthalic anhydride sensitization is generally associated with either an asthma-rhinitis-conjunctivitis syndrome or with a delayed reaction and influenza-like symptoms and with increased IgG and/or phthalic anhydride specific IgE levels in the blood. It is not possible to allocate respiratory sensitisation to different hazard categories based on the response in the sensitisation test. Therefore, respiratory sensitizers are considered in the high hazard category.

Based on the above, Phthalic anhydride is considered an extreme skin and respiratory sensitizer and is allocated to the high hazard category for both routes of exposure.

Phthalic anhydride exists in two forms: the molten state and flakes.

Molten phthalic anhydride is produced at a temperature of approximately ~170°C and is hazardous by virtue of its temperature and specific heat (i.e. danger from scalding). Workers could be exposed via the dermal route and inhalation route.

The flaked product is produced from a cooled thin film of the liquid (either via a conveyor belt or metal drum), and the flakes are produced from the cooled film by means of a blade. In this case, workers could be exposed via the dermal and respiratory route.

Based on the chemical forms of phthalic anhydride, the most likely routes of exposure to phthalic anhydride are *via* dermal contact and inhalation. The oral exposure is not considered to be relevant and would only occur under intentional exposure which is outside the scope of REACH.

There is no consumer use of phthalic anhydride. Phthalic anhydride is not incorporated in any article. It is considered unlikely that humans will be exposed indirectly either by way of contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain, because environmental releases of phthalic anhydride are minimal, and the phthalic acid is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Therefore it is not required to consider the exposure routes for professionals and consumers.

For each exposure scenario and for each use of phthalic anhydride a qualitative risk characterization for sensitization is presented in section 10. This deals with the relevant aspects of exposure as well as the operational conditions and RMMs which are put in place to control the risk of exposure and the risk of sensitization.

Table 57 provides an overview of the exposure scenarios considered for phthalic anhydride. The table also shows the relevant use descriptors assigned for each exposure scenario.

Table 57: Overview on exposure scenarios and coverage of substance life cycle

ES number	Volume (tonnes per annum)	Manufacture	Identified uses			Resulting life cycle stage		Linked to Identified Use	Sector of Use (SU)	Preparation Category (PC)	Process category (PROC)	Article category (AC)	Environmental Release Category
			Formulation	End use	Consumer use	Service life (for articles)	Waste stage						
ES 1 Production	950kt*	Y	n/a	n/a	n/a	n/a	n/a		n.a.	n/a	PROC 1, PROC 2 PROC 8b PROC 9	n/a	ERC 1
ES 2 Intermediate	579.5kt*	N	N	Y	N	n/a	n/a		SU 3 SU 8 SU 9	PC 19	PROC 1, PROC2, PROC 3, PROC 4 PROC 8b, PROC 9	n/a	ERC 6a
ES 3 Monomer	370.5kt*	N	N	Y	N	n/a	n/a		SU 3 SU 10 SU 11 SU 12	PC 32	PROC1, PROC2, PROC 3, PROC4, PROC 8b, PROC 9	n/a	ERC 6c, 6d
ES4 Formulation, mixture, refilling and loading	475kt*	N	Y	N	N	n/a	n/a		SU 3 SU 10	n/a	PROC1, PROC2, PROC3, PROC4, PROC5, PROC 8b, PROC9	n/a	ERC2
ES5 Laboratory chemical	5000 (EU wide tonnage, regional tonnage 500)	N	N	Y	N	n/a	n/a		SU 22	PC 21	PROC 15	n/a	ERC 8A, 8B

* Regional tonnages have been set at the total EU wide production and use level for industrial uses which is a worst case assumption. Local point source environmental emissions for production and industrial uses have been based on the generalised and overestimated worst case tonnage of a large manufacturer/importer (M/I) to take into account the largest possible on site tonnage for a single site. Thus missions for production, intermediate use, use as a monomer and formulation have also been based on known EU/regional tonnages with worst case local tonnages calculated for each application in a conservative worst case manner. Generally a local fraction of 0.1 (10%) of the total EU tonnage is considered to give a worst case estimation of local tonnage based on manufacturer/market data and on-site tonnage levels.

As laboratory use is widespread with a large number of very small point sources the exact tonnage used is difficult to establish. However the amount present on each local source would be less than 1kg by definition. A worst case assumption based on wide dispersive use would be that there are 20 such small sites in a region, each using 5% of the regional tonnage. By default a region has 20,000,000 inhabitants. Each STP catchment has 10000. Therefore, there are 2000 STPs per region. Therefore assuming even distribution of the 20 laboratories (which is an assumption that fits with the wide dispersive nature of the use) it is unlikely that a single STP catchment will contain more than one laboratory and emissions can be determined on this basis. This is still very much a worst case assumption as the amount emitted by any single laboratory will still be vastly in excess of the 1kg which can be located on one site by definition of the ES.

9.1 ES 1: Production of phthalic anhydride

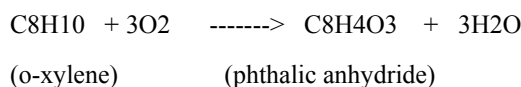
Annual production of Phthalic anhydride in the EU is approximately 950,000t. Of this, 56% (532,000t) is as an intermediate in plasticizer production and 5% (47,500t) for other intermediates (production of isatoic anhydride, intermediates for pigments, dyes, pharmaceuticals and agriculture products). The remainder is used as a monomer: approximately 17% (161,500t) is in the production of Unsaturated Polyester resins (polycondensation using unsaturated dicarboxylic acid, diols and PA), 17% (161,500t) in the production of Alkyd resins (reaction of PA, polyhydric alcohols), and 5% (47,500t) in Polyester polyols, as a plasticizer for PVC.

Phthalic anhydride is manufactured on 17 sites in the EU, with Germany being the principal member state. Production is continuous batch process generally running for up to 360 days/year, with shutdown for planned maintenance.

Each manufacturer will provide detailed descriptions of their manufacturing processes in their individual submissions. The following is a general description.

The technology for the production of phthalic anhydride (PA) is based on the oxidation of orthoxylene (OX) in the gaseous phase with air in the presence of suitable catalyst (fixed bed vanadium based).

The main reaction is as follows:



The technology for the production of phthalic anhydride is based on the well-known (Gibbs) process consisting of:

- Oxidation of o-xylene by means of a fixed bed catalyst (installed inside the reaction tubes). The feed material is delivered to the reactors through pipes.
- Phthalic anhydride is recovered by de-sublimation into switch condensers units.
- Purification is based on heat treatment and distillation/purification section operating under vacuum.
- The exhausted gas is cleaned by suitable technology in accordance to the respective national legislation. High and low-end distillation products are subject to controlled incineration (thermal feedstock for power supply). Aqueous scrubbers convert any phthalic anhydride present to phthalic acid, treated as effluent.
- In addition to the oxidation of o-xylene naphthalene is also used as a feedstock for production of phthalic anhydride. Naphthalene is reacted with oxygen to produce phthalic anhydride with carbon dioxide and water by products.

The product can be sold in molten state as well as in flakes (solid). In the EU, approximately 95% of production is in the molten form, where the liquid phthalic anhydride is transferred by sealed heated pipeline to tanker containers, at approximately 170°C. Phthalic anhydride is maintained in

the liquid state (i.e. above the melting point of 131.6°C) in the tanker container during transport by either steam jacket or internal heating. The intrinsic heat hazard of the liquid form and the need to keep it as a liquid dictates that it is retained within sealed pipelines and vessels at all times.

The flaked product is produced from a cooled thin film of the liquid (either via a conveyor belt or metal drum), and the flakes are produced from the cooled film by means of a blade. Flaking machines are enclosed, with LEV equipment to prevent exposure to dusts. Alternatively, exhausts from the LEV may be fed back to the molten stream, or passed through aqueous scrubbers to convert the phthalic anhydride to phthalic acid. In the EU, approximately 5% of production is in the flaked form.

9.1.1 Exposure scenario

9.1.1.1 Short title of the exposure scenario: Production of phthalic anhydride

Process Categories:

PROC01: Use in closed process, no likelihood of exposure

PROC02: Use in closed, continuous process with occasional controlled exposure

PROC08b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

Environmental Release Category:

ERC01: Production of chemicals

9.1.1.2 Description of activities and processes covered in the exposure scenario

Phthalic anhydride is produced under controlled conditions in high integrity contained systems, with little or no potential for exposure of operators. The chemical reactions and processes as described in 2.1 involve oxidation of o-xylene or naphthalene by means of a fixed bed catalyst (installed inside the reaction tubes). The feed material is delivered to the reactors through pipes. Phthalic anhydride is recovered by de-sublimation into switch condensers units. Purification is based on heat treatment and distillation/purification section operating under vacuum. The exhausted gas is cleaned by suitable technology in accordance to the respective national legislation. High and low-end distillation products are subject to controlled incineration (thermal feedstock for power supply). Aqueous scrubbers or incinerators are used to remove any phthalic anhydride present. The processes are computer controlled, with the supervising operators working in dedicated plant control rooms. The finished product is mostly (95%) produced as molten material (temp ~170°C, melting point phthalic anhydride 131.6°C).

The molten material is hazardous by virtue of its temperature and specific heat (i.e. danger from scalding). It is also important that this high temperature is maintained, to allow the material to remain in the molten state, such that it can be pumped along sealed pipelines, either for direct use, or transfer to tankers (which are also heated, again, to maintain the molten states, in order for the material to be useable by the downstream users). The pipelines and any storage vessels are heated and insulated, and are not open to the atmosphere. This has the dual function of maintaining temperature and preventing worker exposure and release to the environment. Venting of gas from

vessels and tankers can be passed through incinerators or aqueous scrubbers to convert the phthalic anhydride to phthalic acid. Tanker connecting and disconnecting (loading and unloading) generally takes place in the open air. Respiratory equipment and protective clothing are worn when connecting and disconnecting tankers. Gas displacement lines are also used if filling of road tankers takes place under cover.

The flaked product is produced from a cooled thin film of the liquid (either via a conveyor belt or metal drum), and the flakes are produced from the cooled film by means of a blade. Flaking machines are enclosed, with LEV equipment to prevent exposure to dusts (see above). Alternatively, exhausts from the LEV may be fed back to the molten stream, or passed through aqueous scrubbers to convert the phthalic anhydride to phthalic acid. In the EU, approximately 5% of production is in the flaked form. Exposure estimations and risk characterisations are presented below for the flake and molten forms in all cases.

9.1.1.3 Operational conditions related to frequency, duration and amount of use

Table 58: Duration, frequency and amounts

Information type	Data field	Explanation
Use amount per worker [workplace] per day	No data	Worker exposure considered to be negligible for the molten form as it remains enclosed due to the high temperatures. Worker exposure considered to be negligible for the flake form as flakes are produced in closed systems
Duration per day at workplace [for one worker]	8hr/d	Standard number of hours in one work day
Frequency at workplace [for one worker]	220 d/year	Standard number of work days / year
Other determinants related to duration, frequency and amount of use	Intermittent contact is expected	These tasks rarely take a full 8hr / day so worst case is assumed.
Annual amount used per site	95,000 t/y	Worst case on-site tonnage
Emission days per site	360 d/y	Estimated number of emission days, based on continuous production

Remarks or additional information:

Note that there is no professional or consumer use of phthalic anhydride in association with ES1. Note also that phthalic anhydride is not incorporated in any article.

9.1.1.4 Operational conditions related to product characteristics

Table 59: Product Characteristic

Information type	Data field	Explanation
Type of product the information relates to	Substance as such	The product can be sold in the form of flakes or alternatively in liquid form in a sealed tank container.
Physical state of product	Flakes or liquid melt	In the EU, approximately 5% of production is in the flaked form.
For solids: Flaked form	Low dustiness	Considered low due to flake size.
Concentration of substance in product	>99.8 %	The product of the manufacture stage is

Information type	Data field	Explanation
		pure (typically at least 99.8 %)

Remarks or additional information:

Production and handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.

9.1.1.5 Other operational conditions of use

Table 60: Respiration volume and skin contact under conditions of worker uses

Information type	Data field	Explanation
Respiration volume under conditions of use	10m ³ /d	Default value for a worker breathing for a 8hrs work day in RIP 3.2
Skin contact area with the substance under conditions of use	480cm ²	Assumes 2 hands and face only (ECETOC TRA tool)

Table 61: Conditions leading to dilution of initial release related to human health

Information type	Data field	Explanation
Room size and ventilation rate	NA	Not relevant as workers involved in production work in a control room, with no direct contact to the installations housing the material

Table 62: Conditions leading to dilution of initial release related to environment

Information type	Data field	Explanation
Discharge volume of sewage treatment plant	2000 m ³ /d	EUSES default value for standard local STP
Available river water volume to receive the emissions from a site	20,000 m ³ /d	Standard ERC flow rate leading to a 10 fold dilution in receiving waters.

Phthalic anhydride is produced under controlled conditions in high integrity contained systems, with little or no potential for exposure of operators. The chemical reactions and processes involve oxidation of o-xylene by means of a fixed bed catalyst (installed inside the reaction tubes). The feed material is delivered to the reactors through pipes. Phthalic anhydride is recovered by de-sublimation into switch condensers units. Purification is based on heat treatment and distillation/purification section operating under vacuum. The exhausted gas is cleaned by suitable technology in accordance to the respective national legislation. High and low-end distillation products are subject to controlled incineration (thermal feedstock for power supply). Aqueous scrubbers convert any phthalic anhydride present to phthalic acid, treated as effluent. The processes are computer controlled, with the supervising operators working in dedicated plant control rooms.

As noted previously, production and handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.

Installations involved in the production of phthalic anhydride are variously in the open air (outdoor), under cover (i.e. outdoor but with a roof and open sides), and in enclosed buildings. Any gas displaced from containers is conducted via pipeline to be processed i.e. removed and scrubbed and /or filtered. Enclosed buildings have LEV.

Note that there is no consumer use of phthalic anhydride. Note also that phthalic anhydride is not incorporated in any article.

9.1.1.6 Risk management measures

Releases to air, water and waste before risk management are minimised. One major producer has quoted exhaust gas emissions after aqueous scrubbing as approximately 0.02kg/a, and exhaust gas emissions after dust collection in cloth filters as approximately 5 kg/a, from a large production plant. Incineration is also used to reduce atmospheric emissions and is highly effective at minimising loss of phthalic anhydride. In addition to this the sludge from phthalic anhydride STP facilities is either incinerated or sent to specialist landfills. This risk management measure eliminates exposure of agricultural soil, grassland soil and groundwater from the spreading of STP sludge.

Losses to waste water are generally minimal due to the degree of system closure, however, any losses to the waste stream are, at a minimum, treated at an on-site STP/WWTP before being released to the environment or to the municipal STP system. On site pre-treatment may take the form of a standard biological STP with settlement and activated sludge tanks, conversion and chemical neutralisation followed by emission to the municipal STP system or specially constructed wetland settling ponds with sedimentary and plant based removal systems. All these waste stream removal processes are highly efficient with emission concentrations to surface water generally less than 0.1 mg/L. Some measured emissions have been as low as 0.025 mg/L.

Worker exposure is limited by the use of closed systems and relevant PPE and RPE where needed. Specially contained systems are used to transport molten liquid form phthalic anhydride and trained workers wear respirators and chemical resistant clothing and boots where required. LEV is generally employed where required in indoor applications and gas displacement systems may be used in tanker filling under hoods takes place.

Further details of the risk management measures in place for ES1 are below. Note that phthalic anhydride is not used for any consumer use. For the details or exposure and relevant risk characterisation with regards to sensitization please refer to section 10.

Table 63: Risk management measures for industrial site

Information type	Data field	Explanation
Containment and local exhaust ventilation		
Containment plus good work practice required	Effectiveness: Unknown	Production and handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no

Information type	Data field	Explanation
		potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material.
Local exhaust ventilation is not required	Effectiveness : Unknown	Production and handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material.
Personal protective equipment (PPE)		
Type of PPE (gloves, respirator, face-shield etc)	Effectiveness: Unknown	Production and handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Other risk management measures related to workers		
No further risk management measures required		
Risk management measures related to environmental emissions from industrial sites		
Onsite pre-treatment of waste water	Chemical pre-treatment or onsite STP.	Waste waters are generally treated on site by chemical and/or biological methods before release to the municipal STP or to the environment.
Resulting fraction of initially applied amount in waste water released from site to the external sewage system	Varies depending on system. Estimated concentration in the STP effluent is between 2 and 3mg/L based on worst case measured emissions.	Worst case measured production releases are considered below and have been determined to be safe for the environment.
Air emission abatement	Effectiveness: Adequate measures in place	Exhaust gases absorbed in wet scrubbers or removed by incineration. Worst case measured emission values are considered below and are found to be safe for the environment. The emission to air is therefore considered to be negligible.
Resulting fraction of applied amount in waste gas released to environment	43.2 kg/d	Worst case measured values before scrubbing. This value has been inputted into the environmental risk assessment and is determined to be safe for the environment. As such the actual release

Information type	Data field	Explanation
		levels after scrubbing or incineration will pose no threat to the environment.
Onsite waste treatment	Effectiveness: 87.3%	Simpletreat within EUSES assumes 87.3% removal in the STP system. This is considered to be conservative.
Effluent (of the waste water treatment plant) discharge rate	2000 m ³ /d	Default: 2.000 m ³ /d
Recovery of sludge for agriculture or horticulture	No	All sludge is collected and incinerated or sent to landfill.
Resulting fraction of initially applied amount in waste water released from site	12.6%	Simpletreat within EUSES assumes 12.6% emission in effluent from the STP system. This is considered to be conservative.

9.1.1.7 Waste related measures

Table 64: Fractions of substance in waste and waste management measures

Information type	Data field	Explanation
Amount of substances in waste water resulting from identified uses covered in the exposure scenario	40 kg/d	Based on worst case emission to waste waters identified.
Amount of substances in waste resulting from service life of articles	Not applicable	
Type of waste, suitable waste codes	Suitable EWC code(s)	
Type of external treatment aiming at recycling or recovery of substances	None	
Type of external treatment aiming at final disposal of the waste	Incineration or landfill.	
Fraction of substance released into the environment via air from waste handling	Not applicable	
Fraction of substance released into the environment via waste water from waste handling	Not applicable	
Fraction of substance disposed of as secondary waste	Not applicable	

9.1.2 Exposure estimation

9.1.2.1 Workers exposure

Note that there is no EU Workplace Exposure Limit for phthalic anhydride, nor has the German DFG recommended a MAC. Switzerland has established a shift value of 1 mg/m³ and a short-time (15 minutes) value of 1 mg/m³. France has an 8-hour VLEP of 10 mg/Nm³. The present CSR recommends a long-term inhalation DNEL for workers of 32.2 mg/m³ and a dermal DNEL of 10 mg/kg bw/day.

The manufacturers have stated that workers involved in the production of phthalic anhydride are protected by the nature of the installations; use of strictly controlled procedures and sealed pipelines and reactors. Workers perform the same activities throughout the shift. As such, there are no peak exposure points other than connecting and disconnecting tankers, and sampling. Protective clothing

and respiratory equipment are required when connecting/disconnecting tankers, when taking samples and (in combination with a fume cupboard) when analysing samples. It should be noted that the values given below quote the highest data presented by the several members of the Consortium, and therefore represent a worst-case.

Measured data (external to respiratory equipment) from filling tankers with molten phthalic anhydride over 2-7 hour periods showed a recorded mean of 4.19mg/Nm³. Workers wear respiratory protection when loading and unloading tankers which will significantly lessen the actual exposure levels. It is noted that readings taken in the open air are generally not suitable as a basis for safety measures.

Measured data (external to respiratory equipment) from taking samples (maximum daily duration 15 minutes) as 0.78mg/Nm³.

Measured data from loading and sampling of solid (flaked) phthalic anhydride are stated as to be as high as 1.02 mg/Nm³ for a 7 hour working day,

Measured data from laboratory analysis of molten and flaked phthalic anhydride were up to 0.59 mg/Nm³ and 1.57 mg/Nm³ respectively.

9.1.2.1.1 Acute/Short term exposure

Not relevant based on the hazard assessment and therefore will not be assessed.

9.1.2.1.2 Long-term exposure

Tables 66 and 67 show the estimated exposure concentration to workers. The exposure estimates were generated using the ECETOC TRA model using the parameters listed below:

Table 65: Parameters used in ECETOC modelling

	Value used	Explanation/source of data
Molecular weight	148.1156 g/mol	
Vapour Pressure	0.06 Pa	
Water solubility	11200 mg/L	
Partition coefficient octanol-water	logKow = 1.6	
Biodegradability	Readily biodegradable	
Is the substance a solid?	No/Yes	No in case of molten. Yes in case of flake
Dustiness during process	Low	Only in the case of solid
Duration of activity	>4 hours (default)	
Use of ventilation	Indoors without LEV (for PROC 1). Indoors with LEV for other PROCs	

Table 66: Long-term exposure concentrations to workers from molten liquid

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 1	0.343	mg/kg/day
	PROC 2	0.137	mg/kg/day
	PROC 8b	0.686	mg/kg/day
	PROC 9	0.686	mg/kg/day
Inhalation exposure	PROC 1	0.617	mg/m ³
	PROC 2	0.617	mg/m ³
	PROC 8b	0.617	mg/m ³
	PROC 9	0.617	mg/m ³

Table 67: Long-term exposure concentrations to workers from flakes

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 1	0.343	mg/kg/day
	PROC 2	0.137	mg/kg/day
	PROC 8b	0.686	mg/kg/day
	PROC 9	0.686	mg/kg/day
Inhalation exposure	PROC 1	0.01	mg/m ³
	PROC 2	0.001	mg/m ³
	PROC 8b	0.005	mg/m ³
	PROC 9	0.01	mg/m ³

It should be noted that while some of the previously stated measured concentrations are above those estimated by the model, all inhalation exposures (based on standard inhalation of 10 m³ per shift (day) for a 70 kg worker) are significantly below the systemic long term DNEL (see 10.1.1). This is the case for both the molten and flake form.

Measured dermal exposure data are not available. The widespread use of protective clothing (especially industrial gloves and goggles) minimises dermal exposure. There is no dermal exposure to the molten material (see above), and equipment is designed to minimise contact with the flaked material.

9.1.2.2 Consumer exposure

Consumers are not exposed to phthalic anhydride during the production process of ES1.

9.1.2.3 Indirect exposure of humans via the environment (oral)

Environmental releases are shown to be minimal (see below). Phthalic anhydride is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Removal by STP is effective and atmospheric emissions are controlled by scrubbing and/or incineration. Therefore it is considered unlikely that humans will be exposed indirectly either by way of direct contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain.

9.1.2.4 Environmental exposure

First tier conservative environmental exposure estimations were carried out using the EUSES 2.1 tool using the specified ERC defaults. ERC 1 was used to determine the environmental emissions for ES1. Second tier worst case environmental exposure estimations were carried out using EUSES 2.1 to take into account more realistic factors that affect the environmental concentrations and partitioning including degradation, measured values and sorption.

For the environmental assessment industrial categories and use types are chosen to best suit the description of the production and uses of phthalic anhydride and emission defaults are those specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". It was determined that ERC 1 covers the manufacturing stage for phthalic anhydride. In initial assessments for production the figure of 950,000 tpa has been quoted as the maximum tonnage produced in the EU over all sites.

It is proposed that the use of ERC 1 to estimate emissions to the environment will result in an unrealistically harsh assessment for phthalic anhydride. This is because the default emissions fractions in ERC 1 represent a worst case and do not take into account the efficiency of the waste water treatment, sludge removal or atmospheric RMMs. The waste reduction processes are highly efficient. In further higher tier modelling, the worst case known concentrations of the phthalic anhydride in waste water and waste gas are used to refine the PECs.

9.1.2.4.1 Environmental releases

The environmental releases are determined primarily by tonnage and the ERC in the first tier with conservative estimations and defaults being implemented in EUSES. For the second tier assessment in EUSES emission specifications are implemented which accurately description of the production and uses of Phthalic Anhydride while still remaining conservative. Worst case measured emission values are use in all cases. Emission defaults are those specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". Regional data and emission fractions were calculated using EUSES. Full EUSES inputs are shown below.

Table 68: EUSES inputs for ES1

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	148.1156	g/mol	
Vapour Pressure	0.0006	hPa	
Water Solubility	11,200 (average of range)	mg/L	
Octanol/water partition coefficient	1.60	logKow	
Koc	10.84 (estimated)		
Biodegradability	Readily Biodegradable		
Life Cycle Step	Production		
Tonnage (regional)	950,000	Tonnes	
Environmental Release Class	ERC1		
Fraction of Tonnage for Region			1
Fraction of the main local source	0.1		This value has been chosen as a conservative overestimate of the local scale tonnage at a worst case facility. In reality the actual on site tonnages will be less in any single site. Company information has indicated that this value leads to a local tonnage which is higher (and therefore representative) than any actual site. This gives a local tonnage of 95,000 tpa.
STP			Yes
Emission events per year	360 (tier 2 value)	Days	300
Default Release to Air	5	%	5
Default Release to Water	6	%	6
Dilution factor applied for PEC derivation			10 (20,000 m ³ /d)

For the tier 1 assessment of environmental releases the release estimation was based on the tonnage data and the ERC defaults. However the initial first tier calculations were not considered to give a reasonable assessment of the actual emission levels (and were not considered sufficient to demonstrate safe use), and so a tier 2 assessment has been carried out. In order to avoid confusion and to avoid the presentation of multiple tiers of data the first tier calculations which were carried out for ES1 are not presented below.

For the tier 2 assessment of environmental releases the effects of several RMMs have been investigated alongside the worst case measure values obtained from consortium members to cover the uses of phthalic anhydride. For ES1 production the RMMs and measured values taken into account are listed below. The worst case measured emission value to water and the atmosphere

covers all facilities over all ESs for phthalic anhydride. As this emission concentration is obtained from a facility which carries out several processes using phthalic anhydride (and several ESs) it was not possible to define the individual contribution of this emission for each ES. As such the measured value actually takes into account worst case emission levels for several processes (production and intermediate use for example) and as such should be considered to be a worst case assumption which is applicable for all industrial exposure scenarios.

For the tier 2 assessment of environmental releases the effects of several RMMs have been investigated alongside the worst case measure values obtained from consortium members to cover the production uses of phthalic anhydride. For ES1 the RMMs and measured values taken into account are listed below.

Table 69: RMMs and measured values for ES1 tier 2 assessment.

Description of RMM	Details	Effect taken into account in EUSES	Comments
Measured loss to waste water	20 mg/L	Lowering of concentration in STP effluent to 2.53 mg/L	Worst case measured emission value which covers all facilities over all ESs for phthalic anhydride.
Emission and production days	360 emission/production days per year	Increase emission days by 20%.	Continuous production
Sludge removal	Sludge removed to landfill or incinerated.	Concentration in soil due to sludge spreading set to 0.	No contamination of grassland or agricultural soil.
Measured stack gas emissions	Atmospheric losses of 1.8kg/hour.	Emission to the air of 43.2 kg/day.	Worst case emissions prior to scrubbing or incineration. Thus actual emissions to the environment will be even lower.

Table 70 Predicted Releases to the Environment Tier 2

Compartments	Predicted releases	Measured release	Explanation / source of measured data
Release to water	40 kg/d	-	Predicted values are those calculated by EUSES using the worst case measured emissions in waste water.
Release to air	43.2 kg/d	-	Predicted values are those calculated by EUSES using the worst case measured emissions to the atmosphere before scrubbing or incineration.
Soil (direct only) Agricultural soil	0 kd/d	-	No directly loss to soil is expected for this ERC and no sludge spreading.

*The predicted releases were estimated using the EUSES 2.1 program.

9.1.2.4.2 Exposure concentration in sewage treatment plants (STP)

On contact with water, phthalic anhydride is converted to phthalic acid. Therefore the PEC values presented are essentially those for phthalic acid. As the two substances are considered to be suitable for read across purposes, the PECs and PNECs can be considered equivalent. Phthalic anhydride is produced on a large scale, generally on major chemical sites, with dedicated effluent treatment facilities, involving both chemical and biological treatment, coping with many chemical substances. Biodegradation and microbiological toxicity tests have shown that phthalic anhydride (or phthalic acid) is not toxic to microorganisms and is biodegradable. Disposal of sewage sludge is either by controlled high temperature incineration or to landfill. The model appears to predict 87% removal by STP. However actual measured data indicate at least 99.5% removal by STP and the assumptions used in assessing waste removal levels are therefore worst case. Emission fractions from the STP as determined using EUSES are presented in the tables below.

Table 71: Tier 2 Concentrations in sewage

ERC 1 for Compartment:	Estimated exposure concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	unit	value	unit	
Waste water before treatment	-	mg/L	20	mg/L	Measured worst case STP data from consortium members
Sewage (STP effluent)	2.53	mg/L	-	mg/L	
Sludge	51.8	mg/kg			
Local freshwater	0.257	mg/L	-	mg/L	10-fold dilution by receiving waters

Table 72: Conservative emission fractions from the STP

Fraction description	Fraction amount	
	value	unit
Fraction of emission directed to air by STP	0.000138	%
Fraction of emission directed to water by STP	12.6	%
Fraction of emission directed to sludge by STP	0.0102	%
Fraction of emission degraded by STP	87.3	%

9.1.2.4.3 Exposure concentration in the aquatic pelagic compartment

Table 73: Tier 2 Local Concentrations in aquatic pelagic compartment

Compartments	PEC aquatic (local mg/L)	Justification
Freshwater (in mg/l)	0.253	
Marine water (in mg/l)	0.0253	10-fold dilution by receiving waters
Intermittent releases to water (in mg/l)	Not relevant	

Table 74: Tier 2 Predicted Exposure Concentrations (PEC) in aquatic pelagic compartment

Compartments	PEC aquatic (local mg/L)	Justification
Freshwater (in mg/l)	0.257	
Marine water (in mg/l)	0.0258	10-fold dilution by receiving waters
Intermittent releases to water (in mg/l)	Not relevant	

9.1.2.4.4 Exposure concentration in sediments

Phthalic anhydride (phthalic acid) is demonstrated to be present in receiving waters at levels <0.26 mg/L. It is biodegradable, and it can be anticipated that it will be degraded either in the water column, or in the upper aerobic layers of any sediment. Phthalic anhydride and its hydrolysis

product phthalic acid have a log K_{ow} of 1.6 and 0.73, respectively. These values indicate that both substances have a low adsorption potential on sediments (see 7.1). The weight of evidence strongly indicates that phthalic acid will not accumulate in sediments. Nevertheless conservative PECsediment values as calculated by EUSES are presented below.

Table 75: Tier 2 Local Concentrations in aquatic sediment compartment

Compartments	PEC aquatic (local)
Freshwater sediment (in mg/kg wwt)	0.261
Marine sediment (in mg/kg wwt)	0.0258

Table 76: Tier 2 Predicted Exposure Concentrations (PEC) in aquatic sediment compartment

Compartments	PEC aquatic (local)
Freshwater sediment (in mg/kg wwt)	0.261
Marine sediment (in mg/kg wwt)	0.0258

These predictions do not take into account the readily biodegradable nature of phthalic acid, and should therefore be regarded as worst-case.

9.1.2.4.5 Exposure concentrations in soil and groundwater

There is no direct disposal of sewage sludge to soil, as disposal of sewage sludge is either by controlled high temperature incineration or to landfill. Therefore there is no direct exposure to soil or groundwater. Emissions to air are negligible, and therefore indirect emissions to soil (and groundwater) via atmospheric deposition are also negligible. Any phthalic anhydride in the atmosphere will be converted to phthalic acid on contact with atmospheric moisture, and any phthalic acid in rainfall will degrade rapidly on contact with soil. Nonetheless calculated PECs for soil and groundwater are presented below.

Table 77: Tier 2 Local Concentrations in the soil and groundwater compartment

Compartments	PEC (local)
Agricultural soil (averaged over 30 days (in mg/kg))	0.0023
Groundwater (in mg/l)	0.013

Table 78: Tier 2 Predicted Exposure Concentrations (PEC) in the soil and groundwater compartment

Compartments	PEC (local)
Agricultural soil (averaged over 30 days (in mg/kg))	0.0023
Groundwater (in mg/l)	0.013

These predicted values should be assessed in the light of the above statement on sewage sludge, and the information on atmospheric compartment below.

9.1.2.4.6 Atmospheric compartment

As noted previously, emissions to the atmosphere are controlled by either aqueous scrubbers, in which all phthalic anhydride is converted to the soluble phthalic acid, cloth filters or incineration. Removal rates in both cases show an efficiency of >98%.

The maximum value submitted for a stack emission following removal treatment was 2mg/m^3 , with some other values at the analytical limit of $<0.1\text{ mg/Nm}^3$. The residues from the aqueous scrubber are sent to the on-site STP for processing. Stack emissions on an annual basis are estimated to be 5 kg/year from one major production site with almost 100,000 tpa. All methods of removal are considered efficient and adequate.

The measured data can be compared with the tier 1 model predictions and can be used to determine PECs in air based on the worst case measured emissions. . The Tier 1 predictions assume 5% of production is released to atmosphere, which for a plant producing 80,000 tpa is 4,000tpa, or approximately 12 tonnes per day, this is highly unrealistic. Tier 2 concentrations are thus based on the worst case measured stack emissions before gas treatment and are therefore worst case. Tier 1 and Tier 2 local concentrations and PECs for air are shown below.

Table 79: Tier 2 local concentrations in air

	Estimated local exposure concentrations	Explanation / source of data
During emission (mg/m ³)	0.012	Estimated using EUSES 2.1
Annual average (mg/m ³)	0.012	Estimated using EUSES 2.1
Annual deposition (mg/m ² /d)	0.0217	Estimated using EUSES 2.1

Table 80: Tier 2 Predicted Exposure Concentration (PEC) in air

	Local concentration	PEC air (local+regional)	Justification
Annual average PEC in air, total (mg/m ³)	0.012	0.012	Estimated using EUSES 2.1.

9.1.2.4.7 Exposure concentration relevant for the food chain (Secondary poisoning)

Phthalic anhydride is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Removal by STP is effective. Therefore it is considered unlikely that humans will be exposed indirectly either by way of direct contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain.

9.1.2.4.8 Regional exposure levels and environmental concentrations.

Phthalic anhydride may be produced at several sites throughout a region and this may lead to a degree of regional exposure. Regional exposure has been modelled for the production of Phthalic Anhydride using the regional module of EUSES 2.1. No significant PEC values are indicated for the regional scale even under the conservative assumptions of the Tier 2 EUSES assessment.

Table 81: Regional tier 2 concentrations in the environment

	Predicted regional Exposure Concentrations		Measured regional exposure concentrations		Explanation / source of measured data
	PEC value	unit	Measured value	unit	
Freshwater	0.00381	mg/l	NA	mg/l	
Marine water	0.00004	mg/l	NA	mg/l	
Freshwater sediments	0.00339	mg/kg	NA	mg/kg	
Marine sediments	0.00004	mg/kg	NA	mg/kg	
Agricultural soil	0.00136	mg/kg	NA	mg/kg	
Grassland	0.00190	mg/kg	NA	mg/kg	
Air	7.2×10^{-7}	mg/m ³	NA	mg/m ³	

The presented regional PECs above are those generated in the tier 2 assessment with worst case measured emissions taken into account.

9.2 ES 2: Use of phthalic anhydride as an intermediate

Exposure scenario 2 concerns the use of phthalic anhydride as an intermediate by downstream users. The procedures for dealing with the molten material and the flake as an isolated intermediate and in the production will involve very similar procedures to those of production e.g. unloading tankers, piping the molten material to heated storage vessels and/or reactors for use under contained conditions. The processes are computer controlled, with the supervising operators working in dedicated plant control rooms. It is anticipated that the exposure and emission scenarios for these uses will be very similar to production with up to 360 emission days per year.

As with ES1 exposure to workers has been determined using ECETOC TRA and environmental exposure levels have been calculated in EUSES.

9.2.1 Exposure scenario

9.2.1.1 Short title of the exposure scenario: Use of phthalic anhydride as an intermediate

Sectors of Use:

SU3: Industrial uses: Uses of substances as such or in preparation at industrial sites

SU8: Manufacture of bulk, large scale chemicals (including petroleum products)

SU9: Manufacture of fine chemicals

Produce Category:

PC19: Intermediate

Process Categories:

PROC01: Use in closed process, no likelihood of exposure

PROC02: Use in closed, continuous process with occasional controlled exposure

PROC03: Use in closed batch process (synthesis or formulation)

PROC04: Use in batch and other process (synthesis) where opportunity for exposure arises

PROC08B: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

PROC09: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

Environmental Release Category:

ERC6A: Industrial use resulting in manufacture of another substance (use of intermediates)

9.2.1.2 Description of activities and processes covered in the exposure scenario

- (1) The dominant use of phthalic anhydride is as an intermediate. The nature of the material dictates that high-integrity closed systems are used throughout, and that exposures and emissions from use will be essentially similar to or no greater than from production. Phthalic anhydride is used as an intermediate in the formation of unsaturated polyester resins. As such it is transported to the site of use, which may be within the facility of the producer, or involve external transport. On receipt at the site of use, the handling of the material is

essentially similar to the handling of the finished material at the site of production, either as the molten material is transferred from the tanker to a storage vessel (or reactor, if used immediately) via sealed pipelines possibly with sampling for quality control, or as a flake, in IBC, stored in warehouse and used to charge reactors. Handling of the flake at the site of use can be considered as the reverse of the packing in the IBC.

Phthalic anhydride is most commonly used as the saturated acid because it provides an inflexible link and maintains the rigidity in the cured resin.

Phthalic anhydride is also used as an intermediate in the production of the alcoholysis reaction as the basis of the manufacture of phthalate esters, which are widely used plasticizers. The process begins with the reaction of phthalic anhydride with alcohols giving the mixed esters and ends with the second esterification with removal of water.

9.2.1.3 Operational conditions related to frequency, duration and amount of use

Table 82: Duration, frequency and amounts

Information type	Data field	Explanation
Use amount per worker [workplace] per day	No data	Worker exposure considered to be negligible for the molten form as it remains enclosed due to the high temperatures. Worker exposure considered to be negligible for the flake form as flakes are produced in closed systems
Duration per day at workplace [for one worker]	8hr/d	Standard number of hours in one work day
Frequency at workplace [for one worker]	220 d/year	Standard number of work days / year
Other determinants related to duration, frequency and amount of use	Intermittent contact is expected	These tasks rarely take a full 8hr / day so worst case is assumed.
Annual amount used per site	579,500 t/y	Worst case on-site tonnage
Emission days per site	360 d/y	Estimate number of emission days, based on continuous production

Remarks or additional information:

Note that there is no professional or consumer use of phthalic anhydride for this exposure scenario. Note also that phthalic anhydride is not incorporated in any article for this exposure scenario.

9.2.1.4 Operational conditions related to product characteristics

Table 83: Product Characteristic

Information type	Data field	Explanation
Type of product the information relates to	Substance as such	The product can be sold in the form of flakes or alternatively in liquid form in a

Information type	Data field	Explanation
		sealed tank container.
Physical state of product	Flakes or liquid melt	In the EU, approximately 5% of production is in the flaked form.
For solids: Flaked form	Low dustiness	Considered low due to flake size.
Concentration of substance in product	>99.8 %	

Remarks or additional information:

Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in use of phthalic anhydride as an intermediate work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks. Workers handling the flaked product need to employ various Risk Management Measures to reduce exposures. These include enclosed machinery, such that the bags containing the flaked material are emptied under enclosed conditions, with LEV preventing emission of dust; where the potential for dusts cannot be fully avoided, workers will need effective face masks with filters and face/eye/skin protection.

9.2.1.5 Other operational conditions of use

Table 84: Respiration volume and skin contact under conditions of worker uses

Information type	Data field	Explanation
Respiration volume under conditions of use	10m ³ /d	Default value for a worker breathing for a 8hrs work day in RIP 3.2
Skin contact area with the substance under conditions of use	480cm ²	Assumes 2 hands and face only (ECETOC TRA tool)

Table 85: Conditions leading to dilution of initial release related to human health

Information type	Data field	Explanation
Room size and ventilation rate	NA	Not relevant as workers involved in production work in a control room, with no direct contact to the installations housing the material

Table 86: Conditions leading to dilution of initial release related to environment

Information type	Data field	Explanation
Discharge volume of sewage treatment plant	2000 m ³ /d	EUSES default value for standard local STP
Available river water volume to receive the emissions from a site	20,000 m ³ /d	Standard ERC flow rate leading to a 10 fold dilution in receiving waters.

9.2.1.6 Risk management measures

Releases to air, water and waste before risk management are minimised, as with production, as the procedures for handling the molten material are essentially the same for intermediate use as for

production. As noted above workers handling the flaked product need to employ various Risk Management Measures to reduce exposures. These include enclosed machinery, such that the bags containing the flaked material are emptied under enclosed conditions, with LEV preventing emission of dust; where the potential for dusts cannot be fully avoided, workers will need effective face masks with filters and face/eye/skin protection.

Releases to air, water and waste before risk management are minimised. To minimise atmospheric losses aqueous scrubbing, dust collection in cloth filters and incineration are used to reduce atmospheric emissions in a highly effective manner with minimal loss of phthalic anhydride. In addition to this the sludge from phthalic anhydride STP facilities is either incinerated or sent to specialist landfills. This risk management measure eliminates exposure of agricultural soil, grassland soil and groundwater from the spreading of STP sludge.

The inherent high degree of system closure helps to minimise losses to the waste water stream, however any losses to the waste stream are, at a minimum, treated at an on-site STP/WWTP before being released to the environment or to the municipal STP system. On site pre-treatment may take the form of a standard biological STP with settlement and activated sludge tanks, conversion and chemical neutralisation followed by emission to the municipal STP system or specially constructed wetland settling ponds with sedimentary and plant based removal systems. All these waste stream removal processes are highly efficient with emission concentrations to surface water generally similar to those for productions with levels less than 0.1 mg/L. Some measured emissions have been as low as 0.025 mg/L.

The nature of phthalic anhydride that high-integrity closed systems are used throughout, and that exposures and emissions from use will be essentially similar to or no greater than from production. Phthalic anhydride is used as in intermediate in the formation of unsaturated polyester resins. As such it is transported to the site of use, which may be within the facility of the producer, or involve external transport. On receipt at the site of use, the handling of the material is essentially similar to the handling of the finished material at the site of production, either as the molten material is transferred from the tanker to a storage vessel (or reactor, if used immediately) via sealed pipelines possibly with sampling for quality control, or as a flake, in IBC, stored in warehouse and used to charge reactors. Handling of the flake at the site of use can be considered as the reverse of the packing in the IBC.

As noted previously, Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks. Workers handling the flaked product need to employ various Risk Management Measures to reduce exposures. These include enclosed machinery, such that the bags containing the flaked material are emptied under enclosed conditions, with LEV preventing emission of dust; where the potential for dusts cannot be fully avoided, workers will need effective face masks with filters and face/eye/skin protection. For the details or exposure and relevant risk characterisation with regards to sensitization please refer to section 10.

Note that there is no consumer use of phthalic anhydride. Note also that phthalic anhydride is not incorporated in any article.

Table 87: Risk management measures for industrial site

Information type	Data field	Explanation
Containment and local exhaust ventilation		
Containment plus good work practice required	Effectiveness: Unknown	Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material.
Local exhaust ventilation is not required is not required to demonstrate a safe use but may be present depending on the design of the premises	Effectiveness : Unknown	Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material.
Personal protective equipment (PPE)		
Type of PPE (gloves, respirator, face-shield etc)	Effectiveness: Unknown	Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Other risk management measures related to workers		
No further risk management measures required		
Risk management measures related to environmental emissions from industrial sites		
Onsite pre-treatment of waste water	Chemical pre-treatment or onsite STP.	Waste waters are generally treated on site by chemical and/or biological methods before release to the municipal STP or to the environment.
Resulting fraction of initially applied amount in waste water released from site to the external sewage system	Varies depending on system. Estimated concentration in the STP effluent is between 2 and 3mg/L based on worst case measured emissions.	Worst case measured releases for the phthalic anhydride life cycle are considered below and have been determined to be safe for the environment.
Air emission abatement	Effectiveness: Adequate measures in place	Exhaust gases absorbed in wet scrubbers or removed by incineration. Worst case measured emission values are considered below and are found to be safe for the environment. The emission to air is therefore considered to be negligible.

Information type	Data field	Explanation
Resulting fraction of applied amount in waste gas released to environment	43.2 kg/d	Worst case measured values before scrubbing. This value has been inputted into the environmental risk assessment and is determined to be safe for the environment. As such the actual release levels after scrubbing or incineration will pose no threat to the environment.
Onsite waste treatment	Effectiveness: 87.3%	Simpletreat within EUSES assumes 87.3% removal in the STP system. This is considered to be conservative.
Effluent (of the waste water treatment plant) discharge rate	2000 m ³ /d	Default: 2.000 m ³ /d
Recovery of sludge for agriculture or horticulture	None	All sludge is collected and incinerated or sent to landfill.
Resulting fraction of initially applied amount in waste water released from site	12.6%	Simpletreat within EUSES assumes 12.6% emission in effluent from the STP system. This is considered to be overestimated.

9.2.1.7 Waste related measures

Table 88: Fractions of substance in waste and waste management measures

Information type	Data field	Explanation
Amount of substances in waste water resulting from identified uses covered in the exposure scenario	40 kg/d	Based on worst case emission to waste waters identified.
Amount of substances in waste resulting from service life of articles	Not applicable	
Type of waste, suitable waste codes	Suitable EWC code(s)	
Type of external treatment aiming at recycling or recovery of substances	None	
Type of external treatment aiming at final disposal of the waste	Incineration or landfill.	
Fraction of substance released into the environment via air from waste handling	Not applicable	
Fraction of substance released into the environment via waste water from waste handling	Not applicable	
Fraction of substance disposed of as secondary waste	Not applicable	

9.2.2 Exposure estimation

9.2.2.1 Workers exposure

Note that there is no EU Workplace Exposure Limit for phthalic anhydride, nor has the German DFG recommended a MAC. Switzerland has established a shift value of 1 mg/m³ and a short-time (15 minutes) value of 1 mg/m³. France has an 8-hour VLEP of 10 mg/Nm³. The present CSR recommends a long-term inhalation DNEL for workers of 32.2 mg/m³ and a dermal DNEL of 10 mg/kg bw/day.

The manufacturers have stated that workers involved in the handling of phthalic anhydride are protected by the nature of the installations; use of strictly controlled procedures and sealed pipelines and reactors. Workers perform the same activities throughout the shift. As such, there are no peak exposure points other than connecting and disconnecting tankers, and sampling. Protective clothing and respiratory equipment are required when connecting/disconnecting tankers, when taking samples and (in combination with a fume cupboard) when analysing samples.

9.2.2.1.1 Acute/Short term exposure

Not relevant based on the hazard assessment and therefore will not be assessed.

9.2.2.1.2 Long-term exposure

Table 89 shows the estimated exposure concentration to workers. The exposure estimates were generated using the ECETOC TRA model using the parameters listed below:

Table 89: Parameters used in ECETOC modelling

	Value used	Explanation/source of data
Molecular weight	148.1156 g/mol	
Vapour Pressure	0.06 Pa	
Water solubility	11200 mg/L	
Partition coefficient octanol-water	logKow = 1.6	
Biodegradability	Readily biodegradable	
Is the substance a solid?	No/Yes	No in case of molten. Yes in case of flake
Dustiness during process	Low	Only in the case of solid
Duration of activity	>4 hours (default)	
Use of ventilation	Indoors without LEV (for PROC 1). Indoors with LEV for other PROCs	

Table 90: Long-term exposure concentrations to workers from molten liquid

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 1	0.343	mg/kg/day
	PROC 2	0.137	mg/kg/day
	PROC 3	0.0343	mg/kg/day
	PROC 4	0.686	mg/kg/day
	PROC 8b	0.686	mg/kg/day
	PROC 9	0.686	mg/kg/day

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Inhalation exposure	PROC 1	0.617	mg/m3
	PROC 2	0.617	mg/m3
	PROC 3	0.617	mg/m3
	PROC 4	0.617	mg/m3
	PROC 8b	0.617	mg/m3
	PROC 9	0.617	mg/m3

Table 91: Long-term exposure concentrations to workers from flakes

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 1	0.0343	mg/kg/day
	PROC 2	0.137	mg/kg/day
	PROC 3	0.0343	mg/kg/day
	PROC 4	0.686	mg/kg/day
	PROC 8b	0.686	mg/kg/day
	PROC 9	0.686	mg/kg/day
Inhalation exposure	PROC 1	0.01	mg/m3
	PROC 2	0.001	mg/m3
	PROC 3	0.01	mg/m3
	PROC 4	0.05	mg/m3
	PROC 8b	0.005	mg/m3
	PROC 9	0.01	mg/m3

9.2.2.2 Consumer exposure

Consumers are not exposed to phthalic anhydride during the process of ES2.

9.2.2.3 Indirect exposure of humans via the environment (oral)

Environmental releases are shown to be minimal (see below). Phthalic anhydride is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Removal by STP is effective and atmospheric emissions are controlled by scrubbing and/or incineration. Therefore it is considered unlikely that humans will be exposed indirectly either by way of direct contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain.

9.2.2.4 Environmental exposure

The environmental releases for intermediate use are determined primarily by tonnage and the ERC in the first tier with conservative estimations and defaults being implemented in EUSES 2.1. For the second tier assessment in EUSES refined inputs are chosen to best suit the description of the use as an intermediate of Phthalic Anhydride. Emission defaults are those specified by the ECHA “Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation”. Regional data and emission fractions were calculated using EUSES. Full EUSES inputs are shown below.

It is considered that the use of ERC 6A to estimate emissions to the environment from the intermediate use of phthalic anhydride will result in an unrealistically overestimated assessment for phthalic anhydride. This is because the default emissions fractions in ERC 1 represent a worst case and do not take into account the efficiency of the waste water treatment, sludge removal or atmospheric RMMs. The waste reduction processes for phthalic anhydride however are highly efficient. In further higher tier modelling, the worst case known concentrations of the phthalic anhydride in waste water and waste gas are used to refine the PECs.

For ES2 (use as an intermediate) ERC number 6A was used to determine environmental emissions. As a worst case assumption the combined EU use tonnage has been considered in the regional assessment with the local point source tonnage being calculated to represent the worst case on-site tonnage covering all the facilities using phthalic anhydride as an intermediate.

Table 92: EUSES inputs

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	148.1156	g/mol	
Vapour Pressure	0.0006	hPa	
Water Solubility	11,200 (average of range)	mg/L	
Octanol/water partition coefficient	1.60	logKow	
Koc	10.84 (estimated)		
Biodegradability	Readily Biodegradable		
Life Cycle Step	Production		
Tonnage	579,500	Tonnes	
Environmental Release Class	ERC 6A		
Fraction of Tonnage for Region			1
Fraction of the main local source	0.1		This value has been chosen as a conservative overestimate of the local scale tonnage at a worst case facility. In reality the actual on site tonnages will be less in any single site. Company information has indicated that this value leads to a local tonnage which is higher (and therefore representative) than any actual site.
STP			Yes
Emission events per year	360 (tier 2 value)	Days	300
Default Release to Air	ERC 6A: 5	%	ERC 6A: 5
Default Release to Water	ERC 6A: 2	%	ERC 6A: 2
Dilution factor applied for PEC derivation			10 (20,000 m ³ /d)

For the tier 1 assessment of environmental releases the release estimation was based on the tonnage data and the ERC defaults. However the initial first tier calculations were not considered to give a reasonable assessment of the actual emission levels (and were not considered sufficient to demonstrate safe use), and so a tier 2 assessment has been carried out. In order to avoid confusion and to avoid the presentation of multiple tiers of data the first tier calculations which were carried out for ES2 are not presented below.

For the tier 2 assessment of environmental releases the effects of several RMMs have been investigated alongside the worst case measure values obtained from consortium members to cover the uses of phthalic anhydride. For ES2 intermediate use the RMMs and measured values taken into account are listed below. The worst case measured emission value to water and the atmosphere covers all facilities over all ESs for phthalic anhydride. As this emission concentration is obtained

from a facility which carries out several processes using phthalic anhydride (and several ESs) it was not possible to define the individual contribution of this emission for each ES. As such the measured value actually takes into account worst case emission levels for several processes (production and intermediate use for example) and as such should be considered to be a worst case assumption which is applicable for all industrial exposure scenarios.

Table 93: RMMs and measured values for ES2 tier 2 assessment.

Description of RMM	Details	Effect taken into account in EUSES	Comments
Measured loss to waste water	20 mg/L	Lowering of concentration in STP effluent to 2.53 mg/L	Worst case measured emission value which covers all facilities over all ESs for phthalic anhydride.
Emission and production days	360 emission days per year	Increase emission days by 20%.	Continuous intermediate use
Sludge removal	Sludge removed to landfill or incinerated.	Concentration in soil due to sludge spreading set to 0.	No contamination of grassland or agricultural soil.
Measured stack gas emissions	Atmospheric losses of 1.8kg/hour.	Emission to the air of 43.2 kg/day.	Worst case emissions prior to scrubbing or incineration. Thus actual emissions to the environment will be even lower. This emission value covers all facilities over all ESs for phthalic anhydride as it is worst case for all facilities considered.

Table 94 Predicted Releases to the Environment Tier 2

ERC	Compartments	Predicted releases	Measured release	Explanation / source of measured data
6A	Release to water	34 kg/d	-	Predicted values are those calculated by EUSES using the worst case measured emissions in waste water.
	Release to air	43.2 kg/d	-	Predicted values are those calculated by EUSES using the worst case measured emissions to the atmosphere before scrubbing or incineration.
	Soil (direct only) Agricultural soil	0 kd/d	-	No directly loss to soil is expected for this ERC and no sludge spreading.

*The predicted releases were estimated using the EUSES 2.1 program.

9.2.2.4.1 Exposure concentration in sewage treatment plants (STP)

On contact with water, phthalic anhydride is converted to phthalic acid. Therefore the PEC values presented are essentially those for phthalic acid. As the two substances are considered to be suitable for read across purposes, the PECs and PNECs can be considered equivalent. Phthalic anhydride is produced on a large scale, generally on major chemical sites, with dedicated effluent treatment facilities, involving both chemical and biological treatment, coping with many chemical substances. Biodegradation and microbiological toxicity tests have shown that phthalic anhydride (or phthalic acid) is not toxic to microorganisms and is biodegradable. Disposal of sewage sludge is either by controlled high temperature incineration or to landfill. The model appears to predict 87% removal by STP. However actual measured data indicate at least 99.5% removal by STP and the assumptions used in assessing waste removal levels are therefore worst case.

Table 95: Tier 2 Concentrations in sewage

ER C	ERC for Compartment:	Estimated exposure concentrations		Measured exposure concentrations*		Explanation / source of measured data
		value	unit	value	unit	
6A	Waste water before treatment		mg/L	20	mg/L	
	Sewage (STP effluent)	2.53	mg/L		mg/L	
	Sludge	51.8	mg/kg			
	Local freshwater	0.253	mg/L		mg/L	10-fold dilution by receiving waters

Table 96: Conservative emission fractions from the STP

Fraction description	Fraction amount	
	value	unit
Fraction of emission directed to air by STP	0.000138	%
Fraction of emission directed to water by STP	12.6	%
Fraction of emission directed to sludge by STP	0.0102	%
Fraction of emission degraded by STP	87.3	%

9.2.2.4.2 Exposure concentration in the aquatic pelagic compartment

Table 97: Tier 2 Local Concentrations in aquatic pelagic compartment

ERC	Compartments	PEC aquatic (local mg/L)	Justification
6A	Freshwater (in mg/l)	0.215	
	Marine water (in mg/l)	0.0215	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/l)	Not relevant	

Table 98: Tier 2 Predicted Exposure Concentrations (PEC) in aquatic pelagic compartment

ERC	Compartments	PEC aquatic (local mg/L)	Justification
6A	Freshwater (in mg/l)	0.216	
	Marine water (in mg/l)	0.0216	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/l)	Not relevant	

9.2.2.4.3 Exposure concentration in sediments

Phthalic anhydride (phthalic acid) has been measured in receiving waters at levels **<0.1 mg/L**. It is biodegradable, and it can be anticipated that it will be degraded either in the water column, or in the upper aerobic layers of any sediment. Phthalic anhydride and its hydrolysis product phthalic acid have a log K_{ow} of 1.6 and 0.73, respectively. These values indicate that both substances have a low adsorption potential on sediments (see 7.1). The weight of evidence strongly indicates that phthalic acid will not accumulate in sediments. Nevertheless PEC_{sediment} values as calculated by EUSES are presented below. The tier 2 predicted environmental concentrations in sediment are extremely low and suggest that the risk to sediment dwelling organisms from use of Phthalic Anhydride as an intermediate is likely to be negligible.

Table 99: Tier 2 Local Concentrations in aquatic sediment compartment

ERC	Compartments	Concentration
6A	Freshwater sediment (in mg/kg wwt)	0.22
	Marine sediment (in mg/kg wwt)	0.022

Table 100: Tier 2 Predicted Exposure Concentrations (PEC) in aquatic sediment compartment

ERC	Compartments	Concentration
6A	Freshwater sediment (in mg/kg wwt)	0.22
	Marine sediment (in mg/kg wwt)	0.022

These predictions do not take into account the biodegradable nature of phthalic acid, and should therefore be regarded as worst-case.

9.2.2.4.4 Exposure concentrations in soil and groundwater

There is no direct disposal of sewage sludge to soil, as disposal of sewage sludge is either by controlled high temperature incineration or to landfill. Therefore there is no direct exposure to soil or groundwater. Emissions to air are negligible, and therefore indirect emissions to soil (and groundwater) via atmospheric deposition are also negligible. Any phthalic anhydride in the atmosphere will be converted to phthalic acid on contact with atmospheric moisture, and any phthalic acid in rainfall will degrade rapidly on contact with soil. Nonetheless calculated PECs for soil and groundwater are presented below.

Table 101: Tier 2 Local Concentrations in the soil and groundwater compartment

ERC	Compartments	Concentration
6A	Agricultural soil (averaged over 30 days (in mg/kg)	0.0023
	Groundwater (in mg/l)	0.0136

Table 102: Tier 2 Predicted Exposure Concentrations (PEC) in the soil and groundwater compartment

ERC	Compartments	Concentration
6A	Agricultural soil (averaged over 30 days (in mg/kg)	0.0041
	Groundwater (in mg/l)	0.0136

These predicted values should be assessed in the light of the above statement on sewage sludge, and the information on atmospheric compartment below.

9.2.2.4.5 Atmospheric compartment

As noted previously, emissions to the atmosphere are controlled by either aqueous scrubbers, in which all phthalic anhydride is converted to the soluble phthalic acid, cloth filters or incineration. Removal rates in both cases show an efficiency of >98%.

For the atmospheric compartment the Tier 1 predictions assume 5% of used phthalic anhydride is released to atmosphere, which for a plant utilising 80,000 tpa of phthalic anhydride as intermediate is 4,000tpa, or approximately 12 tonnes per day, this is highly unrealistic. Tier 2 concentrations are thus based on the worst case measured stack emissions before gas treatment and are therefore worst case. Tier1 and Tier 2 local concentrations and PECs for air are shown below.

Table 103: Tier 2 local concentrations in air

ERC		Estimated local exposure concentrations	Explanation / source of data
6A	During emission (mg/m ³)	0.012	Estimated using EUSES 2.1
	Annual average (mg/m ³)	0.012	Estimated using EUSES 2.1
	Annual deposition (mg/m ² /d)	0.0217	Estimated using EUSES 2.1

Table 104: Tier 2 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
6A	Annual average PEC in air, total (mg/m ³)	0.012	0.012	Estimated using EUSES 2.1.

9.2.2.4.6 Exposure concentration relevant for the food chain (Secondary poisoning)

Phthalic anhydride is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Removal by STP is effective. Therefore it is considered unlikely that humans will be exposed indirectly either by way of direct contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain.

9.2.2.4.7 Regional exposure levels and environmental concentrations.

Phthalic anhydride may be produced at several sites throughout a region and this may lead to a degree of regional exposure. Regional exposure has been modelled for the production of Phthalic anhydride using the regional module of EUSES 2.1. No significant PEC values are indicated for the regional scale even under the conservative assumptions of the Tier 2 EUSES assessment.

Table 105: Regional concentrations in the environment

ERC6A	Predicted regional Exposure Concentrations		Measured regional exposure concentrations		Explanation / source of measured data
	PEC value	unit	Measured value	unit	
Freshwater	0.00078	mg/l	NA	mg/l	
Marine water	9.2×10^{-6}	mg/l	NA	mg/l	
Freshwater sediments	0.0007	mg/kg	NA	mg/kg	
Marine sediments	8.3×10^{-6}	mg/kg	NA	mg/kg	
Agricultural soil	0.00097	mg/kg	NA	mg/kg	
Grassland	0.0019	mg/kg	NA	mg/kg	
Air	7.2×10^{-7}	mg/m ³	NA	mg/m ³	

9.3 ES 3: Use of phthalic anhydride as a monomer

Exposure scenario 3 relates to use of phthalic anhydride as a monomer by downstream users. However, the procedures for dealing with the molten material and the flake as a monomer will involve very similar procedures to those of production and use as an intermediate. Therefore it is anticipated that the exposure and emission scenarios for these uses will be very similar to those for production of phthalic anhydride with up to 360 days production emission days per year.

The use of phthalic anhydride as a monomer includes the production of alkyl resins which are manufactured using a polymerization reaction between an alcohol, such as glycerol, and a di carboxylic anhydride (phthalic anhydride). Glycerol and phthalic anhydride react to form the polyester glyptal.

A further example of PA use as a monomer is the manufacturing of polyester polyols. This process is very similar to that one described in the alkyl resins manufacturing. The raw materials are phthalic anhydride and polyhydric alcohols. The polyester obtained is not dissolved in any solvent but is used in the formation of polyurethanes particularly polyurethane elastomers, flexible/semi-rigid polyurethane foams and polyurethane coatings. As with previous exposure scenarios worker exposure has been assessed using ECETOC TRA and environmental exposure has been assessed using EUSES 2.1.

9.3.1 Exposure scenario

9.3.1.1.1 Short title of the exposure scenario: Use of phthalic anhydride as a monomer

Sectors of Use:

SU3: Industrial uses: Uses of substances as such or in preparation at industrial sites

SU10: Formulation [mixing] of preparation and/or re-packaging (excluding alloys)

SU12: Manufacture of plastics products, including compounding and conversion

Produce Category:

PC32: Polymer preparations and compounds

Process Categories:

PROC01: Use in closed process, no likelihood of exposure

PROC02: Use in closed, continuous process with occasional controlled exposure

PROC03: Use in closed batch process (synthesis or formulation)

PROC04: Use in batch and other process (synthesis) where opportunity for exposure arises

PROC08B: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

PROC9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

Environmental Release Category:

ERC6C: Industrial use of monomers in the production of plastics (polymers).

ERC6D: Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers.

9.3.1.2 Description of activities and processes covered in the exposure scenario

The procedures for dealing with the molten material and the flake as a monomer will involve very similar procedures to those of production and use as an intermediate. Therefore it is anticipated that the exposure and emission scenarios for these uses will be very similar to those for production of phthalic anhydride with up to 360 days production emission days per year.

The use of phthalic anhydride as a monomer includes the production of alkyd resins which are manufactured using a polymerization reaction between an alcohol, such as glycerol, and a di carboxylic anhydride (phthalic anhydride). Glycerol and phthalic anhydride react to form the polyester glyptal.

A further example of PA use as a monomer is the manufacturing of polyester polyols. This process is very similar to that one described in the alkyd resins manufacturing. The raw materials are phthalic anhydride and polyhydric alcohols. The polyester obtained is not dissolved in any solvent but is used in the formation of polyurethanes particularly polyurethane elastomers, flexible/semi-rigid polyurethane foams and polyurethane coatings.

9.3.1.3 Operational conditions related to frequency, duration and amount of use

Table 106: Duration, frequency and amounts

Information type	Data field	Explanation
Use amount per worker [workplace] per day	No data	Worker exposure considered to be negligible for the molten form as it remains enclosed due to the high temperatures. Worker exposure considered to be negligible for the flake form as flakes are produced in closed systems
Duration per day at workplace [for one worker]	8hr/d	Standard number of hours in one work day
Frequency at workplace [for one worker]	220 d/year	Standard number of work days / year
Other determinants related to duration, frequency and amount of use	Intermittent contact is expected	These tasks rarely take a full 8hr / day so worst case is assumed.
Annual amount used per site	37,500 t/y	Worst case on-site tonnage
Emission days per site	360 d/y	Estimate number of emission days, based on continuous use

Remarks or additional information:

Note that there is no professional or consumer use of phthalic anhydride for this exposure scenario. Note also that phthalic anhydride is not incorporated in any article for this exposure scenario.

9.3.1.4 Operational conditions related to product characteristics

Table 107: Product Characteristic

Information type	Data field	Explanation
Type of product the information relates to	Substance as such	The product can be sold in the form of flakes or alternatively in liquid form in a sealed tank container.

Information type	Data field	Explanation
Physical state of product	Flakes or liquid melt	In the EU, approximately 5% of production is in the flaked form.
For solids: Flaked form	Low dustiness	Considered low due to flake size.
Concentration of substance in product	>99.8 %	

Remarks or additional information:

Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks. Workers handling the flaked product need to employ various Risk Management Measures to reduce exposures. These include enclosed machinery, such that the bags containing the flaked material are emptied under enclosed conditions, with LEV preventing emission of dust; where the potential for dusts cannot be fully avoided, workers will need effective face masks with filters and face/eye/skin protection.

9.3.1.5 Other operational conditions of use

Table 108: Respiration volume and skin contact under conditions of worker uses

Information type	Data field	Explanation
Respiration volume under conditions of use	10m ³ /d	Default value for a worker breathing for a 8hrs work day in RIP 3.2
Skin contact area with the substance under conditions of use	480cm ²	Assumes 2 hands and face only (ECETOC TRA tool)

Table 109: Conditions leading to dilution of initial release related to human health

Information type	Data field	Explanation
Room size and ventilation rate	NA	Not relevant as workers involved in production work in a control room, with no direct contact to the installations housing the material

Table 110: Conditions leading to dilution of initial release related to environment

Information type	Data field	Explanation
Discharge volume of sewage treatment plant	2000 m ³ /d	EUSES default value for standard local STP
Available river water volume to receive the emissions from a site	20,000 m ³ /d	Standard ERC flow rate leading to a 10 fold dilution in receiving waters.

9.3.1.6 Risk management measures

Releases to air, water and waste before risk management are minimised, as with production, as the procedures for handling the molten material are essentially the same for monomer use as for

production. As noted above workers handling the flaked product need to employ various Risk Management Measures to reduce exposures. These include enclosed machinery, such that the bags containing the flaked material are emptied under enclosed conditions, with LEV preventing emission of dust; where the potential for dusts cannot be fully avoided, workers will need effective face masks with filters and face/eye/skin protection.

Releases to air, water and waste before risk management are minimised. To minimise atmospheric losses aqueous scrubbing, dust collection in cloth filters and incineration are used to reduce atmospheric emissions in a highly effective manner with minimal loss of phthalic anhydride. In addition to this the sludge from phthalic anhydride STP facilities is either incinerated or sent to specialist landfills. This risk management measure eliminates exposure of agricultural soil, grassland soil and groundwater from the spreading of STP sludge.

The inherent high degree of system closure helps to minimise losses to the waste water stream, however any losses to the waste stream are, at a minimum, treated at an on-site STP/WWTP before being released to the environment or to the municipal STP system. On site pre-treatment may take the form of a standard biological STP with settlement and activated sludge tanks, conversion and chemical neutralisation followed by emission to the municipal STP system or specially constructed wetland settling ponds with sedimentary and plant based removal systems. All these waste stream removal processes are highly efficient with emission concentrations to surface water generally similar to those for productions with levels less than 0.1 mg/L. Some measured emissions have been stated as less than 0.025mg/L.

The nature of phthalic anhydride that high-integrity closed systems are used throughout, and that exposures and emissions from use will be essentially similar to or no greater than from production. Phthalic anhydride is used as monomer. As such it is transported to the site of use, which may be within the facility of the producer, or involve external transport. On receipt at the site of use, the handling of the material is essentially similar to the handling of the finished material at the site of production, either as the molten material is transferred from the tanker to a storage vessel (or reactor, if used immediately) via sealed pipelines possibly with sampling for quality control, or as a flake, in IBC, stored in warehouse and used to charge reactors. Handling of the flake at the site of use can be considered as the reverse of the packing in the IBC.

As noted previously, Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks. Workers handling the flaked product need to employ various Risk Management Measures to reduce exposures. These include enclosed machinery, such that the bags containing the flaked material are emptied under enclosed conditions, with LEV preventing emission of dust; where the potential for dusts cannot be fully avoided, workers will need effective face masks with filters and face/eye/skin protection. For the details or exposure and relevant risk characterisation with regards to sensitization please refer to section 10.

Note that there is no consumer use of phthalic anhydride. Note also that phthalic anhydride is not incorporated in any article.

Table 111: Risk management measures for industrial site

Information type	Data field	Explanation
Containment and local exhaust ventilation		
Containment plus good work practice required	Effectiveness: Unknown	Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material.
Local exhaust ventilation is not required is not required to demonstrate a safe use but may be present depending on the design of the premises	Effectiveness : Unknown	Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material.
Personal protective equipment (PPE)		
Type of PPE (gloves, respirator, face-shield etc)	Effectiveness: Unknown	Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Other risk management measures related to workers		
No further risk management measures required		
Risk management measures related to environmental emissions from industrial sites		
Onsite pre-treatment of waste water	Chemical pre-treatment or onsite STP.	Waste waters are generally treated on site by chemical and/or biological methods before release to the municipal STP or to the environment.
Resulting fraction of initially applied amount in waste water released from site to the external sewage system	Varies depending on system. Estimated concentration in the STP effluent is between 2 and 3mg/L based on worst case measured emissions.	Worst case measured releases for the phthalic anhydride life cycle are considered below and have been determined to be safe for the environment.
Air emission abatement	Effectiveness: Adequate measures in place	Exhaust gases absorbed in wet scrubbers or removed by incineration. Worst case measured emission values are considered below and are found to be safe for the environment. The emission to air is therefore considered to be negligible.
Resulting fraction of applied amount in waste gas released to environment	43.2 kg/d	Worst case measured values before

Information type	Data field	Explanation
		scrubbing. This value has been inputted into the environmental risk assessment and is determined to be safe for the environment. As such the actual release levels after scrubbing or incineration will pose no threat to the environment.
Onsite waste treatment	Effectiveness: 87.3%	Simpletreat within EUSES assumes 87.3% removal in the STP system. This is considered to be conservative.
Effluent (of the waste water treatment plant) discharge rate	2000 m ³ /d	Default: 2.000 m ³ /d
Recovery of sludge for agriculture or horticulture	None	All sludge is collected and incinerated or sent to landfill.
Resulting fraction of initially applied amount in waste water released from site	12.6%	Simpletreat within EUSES assumes 12.6% emission in effluent from the STP system. This is considered to be overestimated.

9.3.1.7 Waste related measures

Table 112: Fractions of substance in waste and waste management measures

Information type	Data field	Explanation
Amount of substances in waste water resulting from identified uses covered in the exposure scenario	40 kg/d	Based on worst case emission to waste waters identified. Actual emissions are expected to be considerably less.
Amount of substances in waste resulting from service life of articles	Not applicable	
Type of waste, suitable waste codes	Suitable EWC code(s)	
Type of external treatment aiming at recycling or recovery of substances	None	
Type of external treatment aiming at final disposal of the waste	Incineration or landfill.	Sludge removed to landfill or incinerated. No emission to soil.
Fraction of substance released into the environment via air from waste handling	Not applicable	
Fraction of substance released into the environment via waste water from waste handling	Not applicable	
Fraction of substance disposed of as secondary waste	Not applicable	

9.3.2 Exposure estimation

9.3.2.1 Workers exposure

Note that there is no EU Workplace Exposure Limit for phthalic anhydride, nor has the German DFG recommended a MAC. Switzerland has established a shift value of 1 mg/m³ and a short-time (15 minutes) value of 1 mg/m³. France has an 8-hour VLEP of 10 mg/Nm³. The present CSR recommends a long-term inhalation DNEL for workers of 32.2 mg/m³ and a dermal DNEL of 10 mg/kg bw/day.

The manufacturers have stated that workers involved in the handling of phthalic anhydride are protected by the nature of the installations; use of strictly controlled procedures and sealed pipelines and reactors. Workers perform the same activities throughout the shift. As such, there are no peak exposure points other than connecting and disconnecting tankers, and sampling. Protective clothing and respiratory equipment are required when connecting/disconnecting tankers, when taking samples and (in combination with a fume cupboard) when analysing samples. Acute/Short term exposure

Not relevant based on the hazard assessment and therefore will not be assessed.

9.3.2.1.1 Acute/Short-term exposure

Not relevant based on the hazard assessment and therefore will not be assessed.

9.3.2.1.2 Long-term exposure

Table 113 shows the estimated exposure concentration to workers. The exposure estimates were generated using the ECETOC TRA model using the parameters listed below:

Table 113: Parameters used in ECETOC modelling

	Value used	Explanation/source of data
Molecular weight	148.1156 g/mol	
Vapour Pressure	0.06 Pa	
Water solubility	11200 mg/L	
Partition coefficient octanol-water	logKow = 1.6	
Biodegradability	Readily biodegradable	
Is the substance a solid?	No/Yes	No in case of molten. Yes in case of flake
Dustiness during process	Low	Only in the case of solid
Duration of activity	>4 hours (default)	
Use of ventilation	Indoors without LEV (for PROC 1). Indoors with LEV for other PROCs	

Table 114: Long-term exposure concentrations to workers from molten liquid

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 1	0.343	mg/kg/day
	PROC 2	0.137	mg/kg/day
	PROC 3	0.0343	mg/kg/day
	PROC 4	0.686	mg/kg/day
	PROC 8b	0.686	mg/kg/day
	PROC 9	0.686	mg/kg/day
Inhalation exposure	PROC 1	0.617	mg/m3
	PROC 2	0.617	mg/m3
	PROC 3	0.617	mg/m3
	PROC 4	0.617	mg/m3
	PROC 8b	0.617	mg/m3
	PROC 9	0.617	mg/m3

Table 115: Long-term exposure concentrations to workers from flakes

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 1	0.0343	mg/kg/day
	PROC 2	0.137	mg/kg/day
	PROC 3	0.0343	mg/kg/day
	PROC 4	0.686	mg/kg/day
	PROC 8b	0.686	mg/kg/day
	PROC 9	0.686	mg/kg/day
Inhalation exposure	PROC 1	0.01	mg/m3
	PROC 2	0.001	mg/m3
	PROC 3	0.01	mg/m3
	PROC 4	0.05	mg/m3
	PROC 8b	0.005	mg/m3
	PROC 9	0.01	mg/m3

9.3.2.2 Consumer exposure

Consumers are not exposed to phthalic anhydride during the process of ES3.

9.3.2.3 Environmental exposure

The environmental releases are determined primarily by tonnage and the ERC in the first tier with conservative estimations and defaults being implemented in EUSES. For the second tier assessment in EUSES industrial categories and use types are chosen to best suit the description of the use as a monomer of Phthalic Anhydride. Emission defaults are those specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". Regional data and emission fractions were calculated using EUSES. Full EUSES inputs for monomer use are shown below.

For ES3 (use as a monomer) ERC's number 6c and 6d were used to determine environmental emissions.

Table 116: EUSES inputs for environmental assessment

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	148.1156	g/mol	
Vapour Pressure	0.0006	hPa	
Water Solubility	11,200 (average of range)	mg/L	
Octanol/water partition coefficient	1.60	logKow	
Koc	10.84 (estimated)		
Biodegradability	Readily Biodegradable		
Life Cycle Step	Intermediate use		
Tonnage (regional)	370,500	Tonnes	
Environmental Release Classes	ERC6c, 6d		
Fraction of the main local source	0.1		This value has been chosen as a conservative overestimate of the local scale tonnage at a worst case facility. In reality the actual on site tonnages will be less in any single site. Company information has indicated that this value leads to a local tonnage which is higher (and therefore representative) than any actual site. This gives a local tonnage of 37,500 tpa on one site.
STP			Yes
Emission events per year	360	Days	3000
Default Release to Air	ERC 6C:5 ERC 6D: 35	%	ERC 6C:5 ERC 6D: 35
Default Release to Water	ERC 6C:5 ERC 6D:0.005	%	ERC 6C:5 ERC 6D:0.005
Dilution factor applied for PEC derivation			10 (20,000 m ³ /d)

For the tier 1 assessment of environmental releases the release estimation was based on the tonnage data and the ERC defaults. However the initial first tier calculations were not considered to give a reasonable assessment of the actual emission levels (and were not considered sufficient to demonstrate safe use), and so a tier 2 assessment has been carried out. In order to avoid confusion and to avoid the presentation of multiple tiers of data the first tier calculations which were carried out for ES3 are not presented below.

For the tier 2 assessment of environmental releases the effects of several RMMs have been investigated alongside the worst case measure values obtained from consortium members to cover the uses of phthalic anhydride. For ES3 monomer use the RMMs and measured values taken into account are listed below. The worst case measured emission value to water and the atmosphere covers all facilities over all ESs for phthalic anhydride. As this emission concentration is obtained

from a facility which carries out several processes using phthalic anhydride (and several ESs) it was not possible to define the individual contribution of this emission for each ES. As such the measured value actually takes into account worst case emission levels for several processes (production and intermediate use for example) and as such should be considered to be a worst case assumption which is applicable for all industrial exposure scenarios.

For the tier 2 assessment of environmental releases the effects of several RMMs have been investigated alongside the worst case measure values obtained from consortium members to cover the production uses of phthalic anhydride. For ES3 monomer use the RMMs and measured values taken into account are listed below.

Table 117: RMMs and measured values for ES2 tier 2 assessment.

Description of RMM	Details	Effect taken into account in EUSES	Comments
Measured loss to waste water (ERC 6C and 6D only)	20 mg/L	Lowering of concentration in STP effluent to 2.53 mg/L	Worst case measured emission value which covers all facilities over all ESs for phthalic anhydride.
Emission and production days (ERC 6C and 6D only)	360 emission days per year	Increase emission days by 20%.	Continuous intermediate use
Sludge removal	Sludge removed to landfill or incinerated.	Concentration in soil due to sludge spreading set to 0.	No contamination of grassland or agricultural soil.
Measured stack gas emissions	Atmospheric losses of 1.8kg/hour.	Emission to the air of 43.2 kg/day.	Worst case emissions prior to scrubbing or incineration. Thus actual emissions to the environment will be even lower. This emission value covers all facilities over all ESs for phthalic anhydride as it is worst case for all facilities considered.

Table 118 Predicted Releases to the Environment Tier 2

ERC	Compartments	Predicted releases	Measured release	Explanation / source of measured data
6C	Release to water	40 kg/d	-	Predicted values are those calculated by EUSES using the worst case measured emissions in waste water.
	Release to air	43.2 kg/d	-	Predicted values are those calculated by EUSES using the worst case measured emissions to the atmosphere before scrubbing or incineration.
	Soil (direct only) Agricultural soil	0 kd/d	-	No directly loss to soil is expected for this ERC and no sludge spreading.
6D	Release to water	61.8kg/d	-	Predicted values are those calculated by EUSES using the tonnage data and defaults for ERC6D. No refinement required.
	Release to air	43.2 kg/d	-	Predicted values are those calculated by EUSES using the tonnage data and defaults for ERC6D.
	Soil (direct only) Agricultural soil	0 kd/d	-	No directly loss to soil is expected for this ERC and no sludge spreading.

*The predicted releases were estimated using the EUSES 2.1 program.

9.3.2.3.1 Exposure concentration in sewage treatment plants (STP)

On contact with water, phthalic anhydride is converted to phthalic acid. Therefore the PEC values presented are essentially those for phthalic acid. As the two substances are considered to be suitable for read across purposes, the PECs and PNECs can be considered equivalent. Phthalic anhydride is produced on a large scale, generally on major chemical sites, with dedicated effluent treatment facilities, involving both chemical and biological treatment, coping with many chemical substances. Biodegradation and microbiological toxicity tests have shown that phthalic anhydride (or phthalic acid) is not toxic to microorganisms and is biodegradable. Disposal of sewage sludge is either by controlled high temperature incineration or to landfill. The model appears to predict 87% removal by STP. However actual measured data indicate at least 99.5% removal by STP and the assumptions used in assessing waste removal levels are therefore worst case.

Table 119: Tier 2 Concentrations in sewage

ERC	ERC for Compartment:	Estimated exposure concentrations		Measured exposure concentrations*		Explanation / source of measured data
		value	unit	value	unit	
6C	Waste water before treatment		mg/L	20	mg/L	
	Sewage (STP effluent)	2.53	mg/L		mg/L	
	Sludge	51.8	mg/kg			
	Local freshwater	0.253	mg/L		mg/L	10-fold dilution by receiving waters
6D	Waste water before treatment	30.9	mg/L	-	mg/L	Tier 1 value. Refinement not required
	Sewage (STP effluent)	3.9	mg/L		mg/L	Tier 1 value. Refinement not required
	Sludge	78.9	mg/kg			Tier 1 value. Refinement not required
	Local freshwater	0.39	mg/L		mg/L	Tier 1 value. Refinement not required

Table 120: Conservative emission fractions from the STP

Fraction description	Fraction amount	
	value	unit
Fraction of emission directed to air by STP	0.000138	%
Fraction of emission directed to water by STP	12.6	%
Fraction of emission directed to sludge by STP	0.0102	%
Fraction of emission degraded by STP	87.3	%

9.3.2.3.2 Exposure concentration in the aquatic pelagic compartment

Table 121: Tier 2 Local Concentrations in aquatic pelagic compartment

ERC	Compartments	PEC aquatic (local mg/L)	Justification
6C	Freshwater (in mg/l)	0.253	
	Marine water (in mg/l)	0.0253	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/l)	Not relevant	
6D	Freshwater (in mg/l)	0.39	Tier 1 value. Refinement not required.
	Marine water (in mg/l)	0.039	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/l)	Not relevant	

Table 122: Tier 2 Predicted Exposure Concentrations (PEC) in aquatic pelagic compartment

ERC	Compartments	PEC aquatic (local mg/L)	Justification
6C	Freshwater (in mg/l)	0.254	
	Marine water (in mg/l)	0.0250	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/l)	Not relevant	
6D	Freshwater (in mg/l)	0.39	Tier 1 value. Refinement not required.
	Marine water (in mg/l)	0.039	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/l)	Not relevant	

9.3.2.3.3 Exposure concentration in sediments

Phthalic anhydride (phthalic acid) has been measured in receiving waters at levels <0.1 mg/L. It is biodegradable, and it can be anticipated that it will be degraded either in the water column, or in the upper aerobic layers of any sediment. Phthalic anhydride and its hydrolysis product phthalic acid have a log K_{ow} of 1.6 and 0.73, respectively. These values indicate that both substances have a low adsorption potential on sediments (see 7.1). The weight of evidence strongly indicates that phthalic acid will not accumulate in sediments. Nevertheless PEC_{sediment} values as calculated by EUSES are presented below. The tier 2 predicted environmental concentrations in sediment are extremely low and suggest that the risk to sediment dwelling organisms from use of Phthalic Anhydride as a monomer is likely to be negligible.

Table 123: Tier 2 Local Concentrations in aquatic sediment compartment

ERC	Compartments	Concentration
6C	Freshwater sediment (in mg/kg wwt)	0.259
	Marine sediment (in mg/kg wwt)	0.0258
6D	Freshwater sediment (in mg/kg wwt)	0.404 (tier 1 value, no refinement required)
	Marine sediment (in mg/kg wwt)	0.040 (tier 1 value, no refinement required)

Table 124: Tier 2 Predicted Exposure Concentrations (PEC) in aquatic sediment compartment

ERC	Compartments	Concentration
6C	Freshwater sediment (in mg/kg wwt)	0.259
	Marine sediment (in mg/kg wwt)	0.0258
6D	Freshwater sediment (in mg/kg wwt)	0.404 (tier 1 value, no refinement required)
	Marine sediment (in mg/kg wwt)	0.040 (tier 1 value, no refinement required)

These predictions do not take into account the biodegradable nature of phthalic acid, and should therefore be regarded as worst-case.

9.3.2.3.4 Exposure concentrations in soil and groundwater

There is no direct disposal of sewage sludge to soil, as disposal of sewage sludge is either by controlled high temperature incineration or to landfill. Therefore there is no direct exposure to soil or groundwater. Emissions to air are negligible, and therefore indirect emissions to soil (and groundwater) via atmospheric deposition are also negligible. Any phthalic anhydride in the atmosphere will be converted to phthalic acid on contact with atmospheric moisture, and any phthalic acid in rainfall will degrade rapidly on contact with soil. These factors have been taken into account in the tier 2 assessment.

Table 125: Tier 2 Local Concentrations in the soil and groundwater compartment

ERC	Compartments	Concentration
6C	Agricultural soil (averaged over 30 days (in mg/kg))	0.0539
	Groundwater (in mg/l)	0.0624
6D	Agricultural soil (averaged over 30 days (in mg/kg))	0.0816
	Groundwater (in mg/l)	0.0878

Table 126: Tier 2 Predicted Exposure Concentrations (PEC) in the soil and groundwater compartment

ERC	Compartments	Concentration
6C	Agricultural soil (averaged over 30 days (in mg/kg))	0.0559
	Groundwater (in mg/l)	0.0624
6D	Agricultural soil (averaged over 30 days (in mg/kg))	0.0835
	Groundwater (in mg/l)	0.0878

These predicted values should be assessed in the light of the above statement on sewage sludge, and the information on atmospheric compartment below.

9.3.2.3.5 Atmospheric compartment

As noted previously, emissions to the atmosphere are controlled by either aqueous scrubbers, in which all phthalic anhydride is converted to the soluble phthalic acid, cloth filters or incineration. Removal rates in both cases show an efficiency of >98%.

The maximum value submitted for a stack emission following aqueous scrubber treatment was 2mg/m³, with other values at the analytical limit of <0.1 mg/Nm³. The residues from the aqueous scrubber are sent to the on-site STP for processing. Stack emissions on an annual basis are estimated to be 5 kg/year from one major production site (~100,000 tpa).

For the atmospheric compartment the Tier 1 predictions for ERC 6D assume 35% of tonnage is released to atmosphere, which for a plant using 50,000tpa is 17,500tpa, or approximately 50 tonnes per day, this is highly unrealistic. Tier 2 concentrations are thus based on the worst case measured stack emissions before gas treatment and are therefore worst case. Tier1 and Tier 2 local concentrations and PECs for air are shown below.

Table 127: Tier 2 local concentrations in air

ERC		Estimated local exposure concentrations	Explanation / source of data
6C	During emission (mg/m ³)	0.012	Estimated using EUSES 2.1
	Annual average (mg/m ³)	0.0118	Estimated using EUSES 2.1
	Annual deposition (mg/m ² /d)	0.0214	Estimated using EUSES 2.1
6D	During emission (mg/m ³)	0.012	Estimated using EUSES 2.1
	Annual average (mg/m ³)	0.0098	Estimated using EUSES 2.1
	Annual deposition (mg/m ² /d)	0.0178	Estimated using EUSES 2.1

Table 128: Tier 2 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
6C	Annual average PEC in air, total (mg/m ³)	0.012	0.012	Estimated using EUSES 2.1.
6D	Annual average PEC in air, total (mg/m ³)	0.0098	0.0098	Estimated using EUSES 2.1.

9.3.2.3.6 Exposure concentration relevant for the food chain (Secondary poisoning)

Phthalic anhydride is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Removal by STP is effective. Therefore it is considered unlikely that humans will be exposed indirectly either by way of direct contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain.

9.3.2.3.7 Regional exposure levels and environmental concentrations.

Phthalic anhydride may be produced at several sites throughout a region and this may lead to a degree of regional exposure. Regional exposure has been modelled for the production of Phthalic anhydride using the regional module of EUSES 2.1. No significant PEC values are indicated for the regional scale even under the conservative assumptions of the Tier 2 EUSES assessment.

Table 129: Regional concentrations in the environment as determined by EUSES 2.1

ERC 6C	Predicted regional Exposure Concentrations		Measured regional exposure concentrations		Explanation / source of measured data
	PEC value	unit	Measured value	unit	
Freshwater	0.0012	mg/l	NA	mg/l	
Marine water	0.000014	mg/l	NA	mg/l	
Freshwater sediments	0.0011	mg/kg	NA	mg/kg	
Marine sediments	0.000013	mg/kg	NA	mg/kg	
Agricultural soil	0.0001	mg/kg	NA	mg/kg	
Grassland	0.0019	mg/kg	NA	mg/kg	
Air	7.2×10^{-7}	mg/m ³	NA	mg/m ³	

ERC 6D	Predicted regional Exposure Concentrations		Measured regional exposure concentrations		Explanation / source of measured data
	PEC value	unit	Measured value	unit	
Freshwater	0.00002	mg/l	NA	mg/l	
Marine water	4.6×10^{-7}	mg/l	NA	mg/l	
Freshwater sediments	1.7×10^{-5}	mg/kg	NA	mg/kg	
Marine sediments	4.1×10^{-7}	mg/kg	NA	mg/kg	
Agricultural soil	0.00009	mg/kg	NA	mg/kg	
Grassland	0.0018	mg/kg	NA	mg/kg	
Air	7.2×10^{-7}	mg/m ³	NA	mg/m ³	

9.4 ES 4: Formulation, mixture, refilling and reloading of phthalic anhydride

Exposure scenario 4 concerns the use of phthalic anhydride during formulation, mixture, refilling and reloading operations. The procedures for dealing with the molten and flake material include reloading tankers, piping the molten material to fill heated storage vessels and transferring to mixers/blenders to formulate preparations. These operations remain under contained conditions. The processes are computer controlled, with the supervising operators working in dedicated plant control rooms. It is anticipated that the exposure and emission scenarios for these formulation, mixture, reloading and mixing operations uses will be very similar to production with up to 360 emission days per year.

The molten form of phthalic anhydride exists at high temperature and as such contains an intrinsic thermal risk that is controlled by a high degree of system closure. The high temperature conditions also need to be maintained in order to allow the material to remain in the molten state so that it can be pumped along sealed pipelines, either for direct mixing/formulation use, or transfer to containers or tankers (which are also heated or insulated to maintain the molten states, in order for the material to be useable for the processes of this ES by the downstream users). The pipelines and any storage vessels are heated and insulated, and are not open to the atmosphere which reduces atmospheric loss from this ES. The vessel and tanker insulation has the dual function of maintaining temperature and preventing worker exposure and release to the environment.

Any small losses of gas from vessels and tankers (from venting for example) can be passed through catalytic incinerators or aqueous scrubbers to remove any phthalic anhydride from the waste gas. Tanker connecting and disconnecting (loading, unloading and reloading) generally takes place in the open air. Respiratory equipment and protective clothing are worn when connecting and disconnecting tankers. Gas displacement lines are also used if filling of road tankers takes place under cover. In the EU 95% of operations take place using the molten form with use of the flaked form only constituting 5%.

Flaking machines and systems are enclosed, with LEV equipment to prevent exposure to dusts from the flaked form. In some cases exhausts loss from the LEV may be fed back to the molten stream, scrubbed or incinerated. LEV would generally function in the same way for mixing, reloading and refilling of containers with the flake. The nature of the phthalic anhydride dictates that high-integrity closed systems are used throughout.

9.4.1 Exposure scenario

9.4.1.1 Short title of the exposure scenario: Formulation, mixture, refilling and reloading of phthalic anhydride

Sector of Use:

SU3: Industrial uses: Uses of substances as such or in preparation at industrial sites

SU10: Formulation [mixing] of preparation and/or re-packaging (excluding alloys)

Process Categories:

PROC01: Use in closed process, no likelihood of exposure

PROC02: Use in closed, continuous process with occasional controlled exposure

PROC03: Use in closed batch process (synthesis or formulation)

PROC04: Use in batch and other process (synthesis) where opportunity for exposure arises
 PROC05: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)
 PROC08b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
 PROC09: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

Environmental Release Category:

ERC02: Formulation of preparations

9.4.1.2 Description of activities and processes covered in the exposure scenario

The procedures for dealing with the molten and flake material include reloading tankers, piping the molten material to fill heated storage vessels and transferring to mixers/blenders to formulate preparations. These operations remain under contained conditions. The processes are computer controlled, with the supervising operators working in dedicated plant control rooms. It is anticipated that the exposure and emission scenarios for these formulation, mixture, reloading and mixing operations uses will be very similar to production with up to 360 days emission days per year.

The molten form of phthalic anhydride exists at high temperature and as such contains an intrinsic thermal risk that is controlled by a high degree of system closure. The high temperature conditions also need to be maintained in order to allow the material to remain in the molten state so that it can be pumped along sealed pipelines, either for direct mixing/formulation use, or transfer to containers or tankers (which are also heated or insulated to maintain the molten states, in order for the material to be useable for the processes of this ES by the downstream users). The pipelines and any storage vessels are heated and insulated, and are not open to the atmosphere which reduces atmospheric loss from this ES. The vessel and tanker insulation has the dual function of maintaining temperature and preventing worker exposure and release to the environment.

Any small losses of gas from vessels and tankers (from venting for example) can be passed through catalytic incinerators or aqueous scrubbers to remove any phthalic anhydride from the waste gas. Tanker connecting and disconnecting (loading, unloading and reloading) generally takes place in the open air. Respiratory equipment and protective clothing are worn when connecting and disconnecting tankers. Gas displacement lines are also used if filling of road tankers takes place under cover. In the EU 95% of operations take place using the molten form with use of the flaked form only constituting 5%.

Flaking machines and systems are enclosed, with LEV equipment to prevent exposure to dusts from the flaked form. In some cases exhausts loss from the LEV may be fed back to the molten stream, scrubbed or incinerated. LEV would generally function in the same way for mixing, reloading and refilling of containers with the flake. The nature of the phthalic anhydride dictates that high-integrity closed systems are used throughout.

9.4.1.3 Operational conditions related to frequency, duration and amount of use

Table 130: Duration, frequency and amounts

Information type	Data field	Explanation
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Information type	Data field	Explanation
Use amount per worker [workplace] per day	No data	Worker exposure considered to be negligible for the molten form as it remains enclosed due to the high temperatures. Worker exposure considered to be negligible for the flake form as flakes are produced in closed systems
Duration per day at workplace [for one worker]	8hr/d	Standard number of hours in one work day
Frequency at workplace [for one worker]	220 d/year	Standard number of work days / year
Other determinants related to duration, frequency and amount of use	Intermittent contact is expected	These tasks rarely take a full 8hr / day so worst case is assumed.
Annual amount used per site	47,500 t/y	Worst case European production site
Emission days per site	360 d/y	Estimate number of emission days, based on continuous production

Remarks or additional information:

Note that there is no professional or consumer use of phthalic anhydride. Note also that phthalic anhydride is not incorporated in any article.

9.4.1.4 Operational conditions related to product characteristics

Table 131: Product Characteristic

Information type	Data field	Explanation
Type of product the information relates to	Substance as such	The product can be sold in the form of flakes or alternatively in liquid form in a sealed tank container.
Physical state of product	Flakes or liquid melt	In the EU, approximately 5% of production is in the flaked form.
For solids: Flaked form	Low dustiness	Considered low due to flake size.
Concentration of substance in product	>99.8 %	

Remarks or additional information:

Production and handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.

9.4.1.5 Other operational conditions of use

Table 132: Respiration volume and skin contact under conditions of worker uses

Information type	Data field	Explanation
Respiration volume under conditions of use	10m ³ /d	Default value for a worker breathing for a 8hrs work day in RIP 3.2

Skin contact area with the substance under conditions of use	480cm ²	Assumes 2 hands and face only (ECETOC TRA tool)
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Table 133: Conditions leading to dilution of initial release related to human health

Information type	Data field	Explanation
Room size and ventilation rate	NA	Not relevant as workers involved in production work in a control room, with no direct contact to the installations housing the material

Table 134: Conditions leading to dilution of initial release related to environment

Information type	Data field	Explanation
Discharge volume of sewage treatment plant	2000 m ³ /d	EUSES default value for standard local STP
Available river water volume to receive the emissions from a site	20,000 m ³ /d	Standard ERC flow rate leading to a 10 fold dilution in receiving waters.

9.4.1.6 Risk management measures

As the tasks associated with this exposure scenario are carried out at the sites associated with the production, intermediate use and monomer use of phthalic anhydride the risk management measures in place for ES4 will be largely the same as those for previous exposure scenarios. Releases to air, water and waste before risk management are minimised, as with production, as the procedures for handling, formulating, mixing, refilling and reloading the molten material are essentially the same here as for production. As noted above workers handling the flaked product need to employ various Risk Management Measures to reduce exposures. These include enclosed machinery, such that the bags containing the flaked material are emptied under enclosed conditions, with LEV preventing emission of dust; where the potential for dusts cannot be fully avoided, workers will need effective face masks with filters and face/eye/skin protection.

Releases to air, water and waste before risk management are minimised. To minimise atmospheric losses aqueous scrubbing, dust collection in cloth filters and incineration are used to reduce atmospheric emissions in a highly effective manner with minimal loss of phthalic anhydride. In addition to this the sludge from phthalic anhydride STP facilities is either incinerated or sent to specialist landfills. This risk management measure eliminates exposure of agricultural soil, grassland soil and groundwater from the spreading of STP sludge.

The inherent high degree of system closure helps to minimise losses to the waste water stream, however any losses to the waste stream are, at a minimum, treated at an on-site STP/WWTP before being released to the environment or to the municipal STP system. On site pre-treatment may take the form of a standard biological STP with settlement and activated sludge tanks, conversion and chemical neutralisation followed by emission to the municipal STP system or specially constructed wetland settling ponds with sedimentary and plant based removal systems. All these waste stream removal processes are highly efficient with emission concentrations to surface water generally similar to those for productions with levels less than 0.1 mg/L. Some measured emissions have been stated as less than 0.025mg/L.

The nature of phthalic anhydride that high-integrity closed systems are used throughout, and that exposures and emissions from use will be essentially similar to or no greater than from production. Phthalic anhydride is used during formulation, mixture, refilling and reloading operations. The procedures for dealing with the molten and flake material include reloading tankers, piping the molten material to fill heated storage vessels and transferring to mixers/blenders to formulate preparations. These operations remain under contained conditions. The molten form of phthalic anhydride exists at high temperature and as such contains an intrinsic thermal risk that is controlled by a high degree of system closure.

The high temperature conditions also need to be maintained in order to allow the material to remain in the molten state so that it can be pumped along sealed pipelines, either for direct mixing/formulation use, or transfer to containers or tankers (which are also heated or insulated to maintain the molten states, in order for the material to be useable for the processes of this ES by the downstream users). As such it is transported to the site of use, which may be within the facility of the producer, or involve external transport. On receipt at the site of use, the handling of the material is essentially similar to the handling of the finished material at the site of production, either as the molten material is transferred from the tanker to a storage vessel (or reactor, if used immediately) via sealed pipelines possibly with sampling for quality control, or as a flake, in IBC, stored in warehouse and used to charge reactors. Handling of the flake at the site of use can be considered as the reverse of the packing in the IBC.

Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks. Workers handling the flaked product need to employ various Risk Management Measures to reduce exposures. These include enclosed machinery, such that the bags containing the flaked material are emptied under enclosed conditions, with LEV preventing emission of dust; where the potential for dusts cannot be fully avoided, workers will need effective face masks with filters and face/eye/skin protection. For the details or exposure and relevant risk characterisation with regards to sensitization please refer to section 10.

Installations involved in the production of phthalic anhydride are variously in the open air (outdoor), under cover (i.e. outdoor but with a roof and open sides), and in enclosed buildings. Any gas displaced from containers is conducted via pipeline to be processed i.e. removed and scrubbed and /or filtered. Enclosed buildings have LEV.

Note that there is no consumer use of phthalic anhydride. Note also that phthalic anhydride is not incorporated in any article.

Table 135: Risk management measures for industrial site

Information type	Data field	Explanation
Containment and local exhaust ventilation		
Containment plus good work practice required	Effectiveness: Unknown	Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct

Information type	Data field	Explanation
		contact to the installations housing the material.
Local exhaust ventilation is not required is not required to demonstrate a safe use but may be present depending on the design of the premises	Effectiveness : Unknown	Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material.
Personal protective equipment (PPE)		
Type of PPE (gloves, respirator, face-shield etc)	Effectiveness: Unknown	Handling of molten phthalic anhydride involves high temperatures, and high integrity contained systems with little or no potential for exposure. Pipelines and vessels are sealed and insulated. Workers involved in production work in a control room, with no direct contact to the installations housing the material. Workers involved in sampling and transfer of materials to road tankers are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Other risk management measures related to workers		
No further risk management measures required		
Risk management measures related to environmental emissions from industrial sites		
Onsite pre-treatment of waste water	Chemical pre-treatment or onsite STP.	Waste waters are generally treated on site by chemical and/or biological methods before release to the municipal STP or to the environment.
Resulting fraction of initially applied amount in waste water released from site to the external sewage system	Varies depending on system. Estimated concentration in the STP effluent is between 2 and 3mg/L based on worst case measured emissions.	Worst case measured releases for the phthalic anhydride life cycle are considered below and have been determined to be safe for the environment.
Air emission abatement	Effectiveness: Adequate measures in place	Exhaust gases absorbed in wet scrubbers or removed by incineration. Worst case measured emission values are considered below and are found to be safe for the environment. The emission to air is therefore considered to be negligible.
Resulting fraction of applied amount in waste gas released to environment	43.2 kg/d	Worst case measured values before scrubbing. This value has been inputted into the environmental risk assessment and is determined to be safe for the environment. As such the actual release levels after scrubbing or incineration will pose no threat to the environment.
Onsite waste treatment	Effectiveness: 87.3%	Simpletreat within EUSES assumes 87.3% removal in the STP system. This is considered to be conservative.
Effluent (of the waste water treatment	2000 m ³ /d	Default: 2.000 m ³ /d

Information type	Data field	Explanation
plant) discharge rate		
Recovery of sludge for agriculture or horticulture	None	All sludge is collected and incinerated or sent to landfill.
Resulting fraction of initially applied amount in waste water released from site	12.6%	Simpletreat within EUSES assumes 12.6% emission in effluent from the STP system. This is considered to be overestimated.

9.4.1.7 Waste related measures

Table 136: Fractions of substance in waste and waste management measures

Information type	Data field	Explanation
Amount of substances in waste water resulting from identified uses covered in the exposure scenario	40 kg/d	Based on worst case emission to waste waters identified.
Amount of substances in waste resulting from service life of articles	Not applicable	
Type of waste, suitable waste codes	Suitable EWC code(s)	
Type of external treatment aiming at recycling or recovery of substances	None	
Type of external treatment aiming at final disposal of the waste	Incineration or landfill.	
Fraction of substance released into the environment via air from waste handling	Not applicable	
Fraction of substance released into the environment via waste water from waste handling	Not applicable	
Fraction of substance disposed of as secondary waste	Not applicable	

9.4.2 Exposure estimation

9.4.2.1 Workers exposure

Note that there is no EU Workplace Exposure Limit for phthalic anhydride, nor has the German DFG recommended a MAC. Switzerland has established a shift value of 1 mg/m³ and a short-time (15 minutes) value of 1 mg/m³. France has an 8-hour VLEP of 10 mg/Nm³. The present CSR recommends a long-term inhalation DNEL for workers of 32.2 mg/m³ and a dermal DNEL of 10 mg/kg bw/day.

The manufacturers have stated that workers involved in the handling of phthalic anhydride are protected by the nature of the installations; use of strictly controlled procedures and sealed pipelines and reactors. Workers perform the same activities throughout the shift. As such, there are no peak exposure points other than connecting and disconnecting tankers, and sampling. Protective clothing and respiratory equipment are required when connecting/disconnecting tankers, when taking samples and (in combination with a fume cupboard) when analysing samples. Acute/Short term exposure

Not relevant based on the hazard assessment and therefore will not be assessed.

9.4.2.1.1 Long-term exposure

Table 137 shows the estimated exposure concentration to workers. The exposure estimates were generated using the ECETOC TRA model using the parameters listed below:

Table 137: Parameters used in ECETOC modelling

	Value used	Explanation/source of data
Molecular weight	148.1156 g/mol	
Vapour Pressure	0.06 Pa	
Water solubility	11200 mg/L	
Partition coefficient octanol-water	logKow = 1.6	
Biodegradability	Readily biodegradable	
Is the substance a solid?	No/Yes	No in case of molten. Yes in case of flake
Dustiness during process	Low	Only in the case of solid
Duration of activity	>4 hours (default)	
Use of ventilation	Indoors without LEV (for PROC 1). Indoors with LEV for other PROCs	

Table 138: Long-term exposure concentrations to workers from molten liquid

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 1	0.343	mg/kg/day
	PROC 2	0.137	mg/kg/day
	PROC 3	0.0343	mg/kg/day
	PROC 4	0.686	mg/kg/day
	PROC 5	0.0686	mg/kg/day
	PROC 8b	0.686	mg/kg/day
	PROC 9	0.68	mg/kg/day
Inhalation exposure	PROC 1	0.617	mg/m3
	PROC 2	0.617	mg/m3
	PROC 3	0.617	mg/m3
	PROC 4	0.617	mg/m3
	PROC 5	0.617	mg/m3
	PROC 8b	0.617	mg/m3
	PROC 9	0.617	mg/m3

Table 139: Long-term exposure concentrations to workers from flakes

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 1	0.0343	mg/kg/day
	PROC 2	0.137	mg/kg/day
	PROC 3	0.0343	mg/kg/day
	PROC 4	0.686	mg/kg/day
	PROC 5	0.068	mg/kg/day
	PROC 8b	0.686	mg/kg/day
	PROC 9	0.686	mg/kg/day
Inhalation exposure	PROC 1	0.01	mg/m3
	PROC 2	0.001	mg/m3
	PROC 3	0.01	mg/m3
	PROC 4	0.05	mg/m3
	PROC 5	0.05	mg/m3
	PROC 8b	0.005	mg/m3
	PROC 9	0.01	mg/m3

9.4.2.2 Consumer exposure

Consumers are not exposed to phthalic anhydride during the production process of ES4.

9.4.2.3 Indirect exposure of humans via the environment (oral)

Environmental releases are shown to be minimal (see below). Phthalic anhydride is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Removal by STP is effective and atmospheric emissions are controlled by scrubbing and/or incineration. Therefore it is considered unlikely that humans will be exposed indirectly either by way of direct contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain.

9.4.2.4 Environmental exposure

The environmental releases for this use are determined primarily by tonnage and the ERC in the first tier with conservative estimations and defaults being implemented in EUSES 2.1. For the second tier assessment in EUSES refined inputs are chosen to best suit the description of the use as an intermediate of Phthalic Anhydride. Emission defaults are those specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". Regional data and emission fractions were calculated using EUSES. Full EUSES inputs are shown below.

It is considered that the use of ERC 2 to estimate emissions to the environment from the intermediate use of phthalic anhydride will result in an unrealistically overestimated assessment for formulation, mixture, refilling and reloading of phthalic anhydride. This is because the default emissions fractions in ERC 2 represent a worst case and do not take into account the efficiency of the waste water treatment, sludge removal or atmospheric RMMs. The waste reduction processes for phthalic anhydride however are highly efficient. In further higher tier modelling, the worst case known concentrations of the phthalic anhydride in waste water and waste gas are used to refine the PECs. For ES4 ERC 2 was used to determine environmental emissions.

Table 140: EUSES inputs

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	148.1156	g/mol	
Vapour Pressure	0.0006	hPa	
Water Solubility	11,200 (average of range)	mg/L	
Octanol/water partition coefficient	1.60	logKow	
Koc	10.84 (estimated)		
Biodegradability	Readily Biodegradable		
Life Cycle Step	Production		
Tonnage (regional)	475,000	Tonnes	
Environmental Release Class	ERC2		
Fraction of Tonnage for Region			1
Fraction of the main local source	0.1		This value has been chosen as a conservative overestimate of the local scale tonnage at a worst case facility. In reality the actual on site tonnages will be less in any single site. Company information has indicated that this value leads to a local tonnage which is higher (and therefore representative) than any actual site.
STP			Yes
Emission events per year	360 (tier 2 value)	Days	300
Default Release to Air	ERC 2: 2.5	%	ERC 2: 2.5
Default Release to Water	ERC 2: 2	%	ERC 2: 2
Dilution factor applied for PEC derivation			10 (20,000 m ³ /d)

For the tier 1 assessment of environmental releases the release estimation was based on the tonnage data and the ERC defaults. However the initial first tier calculations were not considered to give a reasonable assessment of the actual emission levels (and were not considered sufficient to

demonstrate safe use), and so a tier 2 assessment has been carried out. In order to avoid confusion and to avoid the presentation of multiple tiers of data the first tier calculations which were carried out for ES4 are not presented below.

For the tier 2 assessment of environmental releases the effects of several RMMs have been investigated alongside the worst case measure values obtained from consortium members to cover the uses of phthalic anhydride. For ES4 the RMMs and measured values taken into account are listed below. The worst case measured emission value to water and the atmosphere covers all facilities over all ESs for phthalic anhydride. As this emission concentration is obtained from a facility which carries out several processes using phthalic anhydride (and several ESs) it was not possible to define the individual contribution of this emission for each ES. As such the measured value actually takes into account worst case emission levels for several processes (production and intermediate use for example) and as such should be considered to be a worst case assumption which is applicable for all industrial exposure scenarios.

For the tier 2 assessment of environmental releases the effects of several RMMs have been investigated alongside the worst case measure values obtained from consortium members to cover the production uses of phthalic anhydride. For ES4 the RMMs and measured values taken into account are listed below.

Table 141: RMMs and measured values for ES4 tier 2 assessment.

Description of RMM	Details	Effect taken into account in EUSES	Comments
Measured loss to waste water	20 mg/L	Lowering of concentration in STP effluent to 2.53 mg/L	Worst case measured emission value.
Emission and production days	360 emission days per year	Increase emission days by 20%.	Continuous intermediate use
Sludge removal	Sludge removed to landfill or incinerated.	Concentration in soil due to sludge spreading set to 0.	No contamination of grassland or agricultural soil.
Measured stack gas emissions	Atmospheric losses of 1.8kg/hour.	Emission to the air of 43.2 kg/day.	Worst case emissions prior to scrubbing or incineration. Thus actual emissions to the environment will be even lower. This emission value covers all facilities over all ESs for phthalic anhydride as it is worst case for all facilities considered.

Table 142 Predicted Releases to the Environment Tier 2

ERC	Compartments	Predicted releases	Measured release	Explanation / source of measured data
2	Release to water	40 kg/d	-	Predicted values are those calculated by EUSES using the worst case measured emissions in waste water.
	Release to air	43.2 kg/d	-	Predicted values are those calculated by EUSES using the worst case measured emissions to the atmosphere before scrubbing or incineration.
	Soil (direct only) Agricultural soil	0 kd/d	-	No directly loss to soil is expected for this ERC and no sludge spreading.

*The predicted releases were estimated using the EUSES 2.1 program.

9.4.2.4.1 Exposure concentration in sewage treatment plants (STP)

On contact with water, phthalic anhydride is converted to phthalic acid. Therefore the PEC values presented are essentially those for phthalic acid. As the two substances are considered to be suitable for read across purposes, the PECs and PNECs can be considered equivalent. Phthalic anhydride is produced on a large scale, generally on major chemical sites, with dedicated effluent treatment facilities, involving both chemical and biological treatment, coping with many chemical substances. Biodegradation and microbiological toxicity tests have shown that phthalic anhydride (or phthalic acid) is not toxic to microorganisms and is biodegradable. Disposal of sewage sludge is either by controlled high temperature incineration or to landfill. The model appears to predict 87% removal by STP. However actual measured data indicate at least 99.5% removal by STP and the assumptions used in assessing waste removal levels are therefore worst case.

Table 143: Tier 2 Concentrations in sewage

ERC	ERC for Compartment:	Estimated exposure concentrations		Measured exposure concentrations*		Explanation / source of measured data
		value	unit	value	unit	
2	Waste water before treatment		mg/L	20	mg/L	Measured worst case data from consortium members
	Sewage (STP effluent)	2.53	mg/L		mg/L	
	Sludge	51.8	mg/kg			
	Local freshwater	0.253	mg/L		mg/L	10-fold dilution by receiving waters

Table 144: Conservative emission fractions from the STP

Fraction description	Fraction amount	
	value	unit
Fraction of emission directed to air by STP	0.000138	%
Fraction of emission directed to water by STP	12.6	%
Fraction of emission directed to sludge by STP	0.0102	%
Fraction of emission degraded by STP	87.3	%

9.4.2.4.2 Exposure concentration in the aquatic pelagic compartment

Table 145: Tier 2 Local Concentrations in aquatic pelagic compartment

ERC	Compartments	PEC aquatic (local mg/L)	Justification
2	Freshwater (in mg/l)	0.253	
	Marine water (in mg/l)	0.0253	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/l)	Not relevant	

Table 146: Tier 2 Predicted Exposure Concentrations (PEC) in aquatic pelagic compartment

ERC	Compartments	PEC aquatic (local mg/L)	Justification
2	Freshwater (in mg/l)	0.254	
	Marine water (in mg/l)	0.0258	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/l)	Not relevant	

9.4.2.4.3 Exposure concentration in sediments

Phthalic anhydride (phthalic acid) has been measured in receiving waters at levels <0.1 mg/L (with one measured emission at less than 0.025mg/L). It is biodegradable, and it can be anticipated that it will be degraded either in the water column, or in the upper aerobic layers of any sediment. Phthalic anhydride and its hydrolysis product phthalic acid have a log K_{ow} of 1.6 and 0.73, respectively. These values indicate that both substances have a low adsorption potential on sediments (see 7.1). The weight of evidence strongly indicates that phthalic acid will not accumulate in sediments. Nevertheless PECsediment values as calculated by EUSES are presented below. The tier 2 predicted environmental concentrations in sediment are extremely low and suggest that the risk to sediment dwelling organisms from use of Phthalic Anhydride during formulation, refilling, reloading and mixing is negligible.

Table 147: Tier 2 Local Concentrations in aquatic sediment compartment

ERC	Compartments	Concentration
2	Freshwater sediment (in mg/kg wwt)	0.26
	Marine sediment (in mg/kg wwt)	0.0253

Table 148: Tier 2 Predicted Exposure Concentrations (PEC) in aquatic sediment compartment

ERC	Compartments	Concentration
2	Freshwater sediment (in mg/kg wwt)	0.258
	Marine sediment (in mg/kg wwt)	0.0258

These predictions do not take into account the biodegradable nature of phthalic acid, and should therefore be regarded as worst-case.

9.4.2.4.4 Exposure concentrations in soil and groundwater

There is no direct disposal of sewage sludge to soil, as disposal of sewage sludge is either by controlled high temperature incineration or to landfill. Therefore there is no direct exposure to soil or groundwater. Emissions to air are negligible, and therefore indirect emissions to soil (and groundwater) via atmospheric deposition are also negligible. Any phthalic anhydride in the atmosphere will be converted to phthalic acid on contact with atmospheric moisture, and any phthalic acid in rainfall will degrade rapidly on contact with soil. Nonetheless calculated PECs for soil and groundwater are presented below.

Table 149: Tier 2 Local Concentrations in the soil and groundwater compartment

ERC	Compartments	Concentration
2	Agricultural soil (averaged over 30 days (in mg/kg)	0.0539
	Groundwater (in mg/l)	0.062

Table 150: Tier 2 Predicted Exposure Concentrations (PEC) in the soil and groundwater compartment

ERC	Compartments	Concentration
2	Agricultural soil (averaged over 30 days (in mg/kg)	0.0558
	Groundwater (in mg/l)	0.062

These predicted values should be assessed in the light of the above statement on sewage sludge, and the information on atmospheric compartment below.

9.4.2.4.5 Atmospheric compartment

As noted previously, emissions to the atmosphere are controlled by either aqueous scrubbers, in which all phthalic anhydride is converted to the soluble phthalic acid, cloth filters or incineration. Removal rates in both cases show an efficiency of >98%.

For the atmospheric compartment the Tier 1 predictions assume 2.5% of formulated substance is released to atmosphere, which for a plant formulating 50,000 tpa is 1,250 tpa, or approximately 3.5 tonnes per day, this is highly unrealistic. Tier 2 concentrations are thus based on the worst case measured stack emissions before gas treatment and are therefore worst case. Tier1 and Tier 2 local concentrations and PECs for air are shown below.

Table 151: Tier 2 local concentrations in air

ERC		Estimated local exposure concentrations	Explanation / source of data
2	During emission (mg/m ³)	0.012	Estimated using EUSES 2.1
	Annual average (mg/m ³)	0.0118	Estimated using EUSES 2.1
	Annual deposition (mg/m ² /d)	0.0214	Estimated using EUSES 2.1

Table 152: Tier 2 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
2	Annual average PEC in air, total (mg/m ³)	0.012	0.012	Estimated using EUSES 2.1.

9.4.2.4.6 Exposure concentration relevant for the food chain (Secondary poisoning)

Phthalic anhydride is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Removal by STP is effective. Therefore it is considered unlikely that humans will be exposed indirectly either by way of direct contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain.

9.4.2.4.7 Regional exposure levels and environmental concentrations.

Phthalic anhydride may be produced at several sites throughout a region and this may lead to a degree of regional exposure. Regional exposure has been modelled for the production of Phthalic anhydride using the regional module of EUSES 2.1. No significant PEC values are indicated for the regional scale even under the conservative assumptions of the Tier 2 EUSES assessment.

Table 153: Regional concentrations in the environment

ERC2	Predicted regional Exposure Concentrations		Measured regional exposure concentrations		Explanation / source of measured data
	PEC value	unit	Measured value	unit	
Freshwater	0.0006	mg/l	NA	mg/l	
Marine water	7.6×10^{-6}	mg/l	NA	mg/l	
Freshwater sediments	0.00057	mg/kg	NA	mg/kg	
Marine sediments	6.88×10^{-6}	mg/kg	NA	mg/kg	
Agricultural soil	0.0009	mg/kg	NA	mg/kg	
Grassland	0.0019	mg/kg	NA	mg/kg	
Air	7.2×10^{-7}	mg/m ³	NA	mg/m ³	

9.5 ES 5: Use of phthalic anhydride as a laboratory chemical

Exposure scenario 5 concerns the small scale use of phthalic anhydride as a laboratory chemical. As the majority of laboratories involved would generally not use phthalic anhydride in the molten form (due to not having the specialised systems in place to deal with the molten form of phthalic anhydride) the solid (flaked form) use would generally be most prevalent in the laboratory. The amounts used on each site would generally be very small with less than 1kg per site. As such this exposure scenario can be considered to be wide dispersive with a large number of very small point sources (individual laboratories) throughout the EU being encompassed in this use.

As such the focus of this ES should be on the regional risk as specified by the ECHA “Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation”.

As with previous exposure scenarios exposure to workers has been determined using ECETOC TRA and environmental exposure levels have been calculated in EUSES.

9.5.1 Exposure scenario

9.5.1.1 Short title of the exposure scenario: **Use of phthalic anhydride as a laboratory chemical**

Sector of Use:

SU22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Process Categories:

PROC15: Use as laboratory reagent

Product Categories:

PC21: Laboratory chemicals

Environmental Release Category:

ERC8A: Wide dispersive indoor use of processing aids in open systems

ERC8B: Wide dispersive indoor use of reactive substances in open systems

9.5.1.2 Description of activities and processes covered in the exposure scenario

As the majority of laboratories involved would generally not use phthalic anhydride in the molten form (due to not having the specialised systems in place to deal with the molten form of phthalic anhydride) the solid (flaked form) use would generally be most prevalent in the laboratory. The amounts used on each site would generally be very small with less than 1kg per site. As such this exposure scenario can be considered to be wide dispersive with a large number of very small point sources (individual laboratories) throughout the EU being encompassed in this use. The uses of

phthalic anhydride in small scale laboratories may be many and specialised however at some of the uses would be in chemical reactions similar to those described for intermediate and monomer use (for example the formations of alkyl resins). In addition to this phthalic anhydride is recognised as an important precursor in the preparation of phthalate esters and as a precursor for reagents used in organic synthesis.

During laboratory use exhaust gasses can be filtered and scrubbed; typically this would remove >99% of released phthalic anhydride. Laboratory workers involved in handling and use of phthalic anhydride are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks. Waste stream treatment may also be employed to reduce environmental exposure through the laboratories specialised waste treatment system which would be tailored to deal with generalised chemical waste.

9.5.1.3 Operational conditions related to frequency, duration and amount of use

Table 154: Duration, frequency and amounts

Information type	Data field	Explanation
Use amount per worker [workplace] per day	No data	Not specified due to wide range of uses
Duration per day at workplace [for one worker]	8hr/d	Standard number of hours in one work day
Frequency at workplace [for one worker]	220 d/year	Standard number of work days / year
Other determinants related to duration, frequency and amount of use	Intermittent contact is expected	These tasks rarely take a full 8hr / day so worst case is assumed.
Annual amount used per site	No data	Less than 1 Kg present per site at one time
Emission days per site	300 d/y	Estimate number of emission days, based on continuous production

Remarks or additional information:

Note that there is no consumer use of phthalic anhydride. Note also that phthalic anhydride is not incorporated in any article.

9.5.1.4 Operational conditions related to product characteristics

Table 155: Product Characteristic

Information type	Data field	Explanation
Type of product the information relates to	Substance as such	The solid flake form would be prevalent in the laboratory due to not having the specialised systems in place to deal with the molten form of phthalic anhydride
Physical state of product	Flakes	The solid flake form would be prevalent in the laboratory due to not having the specialised systems in place to deal with the molten form of phthalic anhydride
For solids: Flaked form	Low dustiness	Considered low due to flake size.
Concentration of substance in product	>99.8 %	

Remarks or additional information:

Laboratory workers involved in handling and use of phthalic anhydride are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.

9.5.1.5 Other operational conditions of use

Table 156: Respiration volume and skin contact under conditions of worker uses

Information type	Data field	Explanation
Respiration volume under conditions of use	10m ³ /d	Default value for a worker breathing for a 8hrs work day in RIP 3.2
Skin contact area with the substance under conditions of use	480cm ²	Assumes 2 hands and face only (ECETOC TRA tool)

Table 157: Conditions leading to dilution of initial release related to human health

Information type	Data field	Explanation
Room size and ventilation rate	NA	This would vary between laboratories. However there would be local exhaust ventilation (e.g. fumehoods)

Table 158: Conditions leading to dilution of initial release related to environment

Information type	Data field	Explanation
Discharge volume of sewage treatment plant	2000 m ³ /d	EUSES default value for standard local STP
Available river water volume to receive the emissions from a site	20,000 m ³ /d	Standard ERC flow rate leading to a 10 fold dilution in receiving waters.

9.5.1.6 Risk management measures

The uses of phthalic anhydride in small scale laboratories may be many and specialised however at some of the uses would be in chemical reactions similar to those described for intermediate and monomer use (for example the formations of alkyl resins). In addition to this phthalic anhydride is recognised as an important precursor in the preparation of phthalate esters and as a precursor for reagents used in organic synthesis.

During laboratory use exhaust gasses can be filtered and scrubbed; typically this would remove >99% of released phthalic anhydride. Laboratory workers involved in handling and use of phthalic anhydride are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks. Waste stream treatment may also be employed to reduce environmental exposure through the laboratories specialised waste treatment system which would be tailored to deal with generalised chemical waste.

As noted previously, during laboratory use exhaust gasses can be filtered and scrubbed; typically this would remove >99% of released phthalic anhydride. Laboratory workers involved in handling and use of phthalic anhydride are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks. Waste stream treatment

may also be employed to reduce environmental exposure through the laboratories specialised waste treatment system which would be tailored to deal with generalised chemical waste.

Note that there is no consumer use of phthalic anhydride. Note also that phthalic anhydride is not incorporated in any article. Due to the high temperatures required and the specialised machinery involved laboratory use would generally not involve the molten form.

For the details of exposure and relevant risk characterisation with regards to sensitization please refer to section 10.

With regards to environmental emissions there may be specialised waste treatment employed which could take the form of effluent/waste capture or on site STP facilities. If these systems are not in place the municipal STP is considered sufficient to deal with the limited small point source emissions from this wide dispersive use.

Table 159: Risk management measures for industrial site

Information type	Data field	Explanation
Containment and local exhaust ventilation		
Containment is not required to demonstrate a safe use but may be present depending on the design of the laboratories. Good work practice required	Effectiveness: Unknown	Laboratory workers involved in handling and use of phthalic anhydride are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Local exhaust ventilation is not required to demonstrate a safe use but may be present depending on the design of the laboratories.	Effectiveness : Unknown	Laboratory workers involved in handling and use of phthalic anhydride are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Personal protective equipment (PPE)		
Type of PPE (gloves, respirator, face-shield etc)	Effectiveness: Unknown	Laboratory workers involved in handling and use of phthalic anhydride are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Other risk management measures related to workers		
No further risk management measures required		
Risk management measures related to environmental emissions from laboratories		
Onsite pre-treatment of waste water	Possible on-site treatment	Laboratories may have on site waste treatment, however the quantities used in the laboratory are so small that this may not be required for phthalic anhydride use.
Resulting fraction of initially applied amount in waste water released from site to the external sewage system	Varies depending on system.	This will change depending on the use pattern in the laboratory concerned. The worst case assumed emissions have been considered in tier 1 and found to be safe.
Air emission abatement	Effectiveness: Adequate measures in place	LEV (fume hoods) are generally in place in most laboratories.
Resulting fraction of applied amount in	88.3 kg/d	

Information type	Data field	Explanation
waste gas released to environment		Worst case EUSES estimated value (as there is only <1kg on site for each laboratory this value is a vast overestimation.
Onsite waste treatment	Effectiveness: 87.3%	Simpletreat within EUSES assumes 87.3% removal in the STP system. This is considered to be conservative and is applicable to the municipal STP and laboratory use.
Effluent (of the waste water treatment plant) discharge rate	2000 m ³ /d	Default: 2.000 m ³ /d
Recovery of sludge for agriculture or horticulture	None	All sludge is collected and incinerated or sent to landfill.
Resulting fraction of initially applied amount in waste water released from site	12.6%	Simpletreat within EUSES assumes 12.6% emission in effluent from the STP system. This is considered to be overestimated.

9.5.1.7 Waste related measures

Table 160: Fractions of substance in waste and waste management measures

Information type	Data field	Explanation
Amount of substances in waste water resulting from identified uses covered in the exposure scenario	88.3 kg/d	Based on worst case estimation in EUSES.
Amount of substances in waste resulting from service life of articles	Not applicable	
Type of waste, suitable waste codes	Suitable EWC code(s)	
Type of external treatment aiming at recycling or recovery of substances	None	
Type of external treatment aiming at final disposal of the waste	Not required for phthalic anhydride as the risk is minimal.	
Fraction of substance released into the environment via air from waste handling	Not applicable	
Fraction of substance released into the environment via waste water from waste handling	Not applicable	
Fraction of substance disposed of as secondary waste	Not applicable	

9.5.2 Exposure estimation

9.5.2.1 Workers exposure

Note that there is no EU Workplace Exposure Limit for phthalic anhydride, nor has the German DFG recommended a MAC. Switzerland has established a shift value of 1 mg/m³ and a short-time (15 minutes) value of 1 mg/m³. France has an 8-hour VLEP of 10 mg/Nm³. The present CSR recommends a long-term inhalation DNEL for workers of 32.2 mg/m³ and a dermal DNEL of 10 mg/kg bw/day.

Laboratory workers involved in handling and use of phthalic anhydride are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks. It should be noted that the values given below quote the highest data presented by the several members of the Consortium, and therefore represent a worst-case.

9.5.2.1.1 Acute/Short term exposure

Not relevant based on the hazard assessment and therefore will not be assessed.

9.5.2.1.2 Long-term exposure

Table 161 shows the estimated exposure concentration to workers. The exposure estimates were generated using the ECETOC TRA model using the parameters listed below:

Table 161: Parameters used in ECETOC modelling

	Value used	Explanation/source of data
Molecular weight	148.1156 g/mol	
Vapour Pressure	0.06 Pa	
Water solubility	11200 mg/L	
Partition coefficient octanol-water	logKow = 1.6	
Biodegradability	Readily biodegradable	
Is the substance a solid?	No/Yes	No in case of molten. Yes in case of flake
Dustiness during process	Low	Only in the case of solid
Duration of activity	>4 hours (default)	
Use of ventilation	Indoors without LEV (for PROC 1). Indoors with LEV for other PROCs	

Table 162: Long-term exposure concentrations to workers from molten liquid

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 15	0.0343	mg/kg/day
Inhalation exposure	PROC 15	0.617	mg/m ³

Table 163: Long-term exposure concentrations to workers from flakes

Routes of exposure	PROC	Estimated Exposure Concentrations	
		value	unit
Dermal exposure	PROC 15	0.0343	mg/kg/day
Inhalation exposure	PROC 15	0.01	mg/m ³

9.5.2.2 Consumer exposure

Consumers are not exposed to phthalic anhydride during the production process of ES5.

9.5.2.3 Indirect exposure of humans via the environment (oral)

Environmental releases are shown to be minimal (see below). Phthalic anhydride is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Removal by STP is effective and atmospheric emissions are controlled by scrubbing and/or incineration. Therefore it is considered unlikely that humans will be exposed indirectly either by way of direct contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain.

9.5.2.4 Environmental exposure

The environmental releases for laboratory use are determined primarily by tonnage and the ERC in as specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". Regional data and emission fractions were calculated using EUSES. Full EUSES inputs are shown below.

It is considered that though the use of ERC 8A and 8B to estimate emissions to the environment from the intermediate use of phthalic anhydride will result in an unrealistically overestimated assessment for phthalic anhydride safe use is nevertheless demonstrated. Given that the actual amount on site in any one laboratory is expected to be less than 1kg it can be seen that the assumptions of ERC 8A and 8B vastly overestimate the emissions. Despite this the first tier conservative assessment has demonstrated no risk and shows that laboratory use of phthalic anhydride poses no risk to the environment.

For ES5 (use as a laboratory chemical) ERC's number 8A and 8B were used to determine estimated environmental emissions. It is likely that laboratories which use phthalic anhydride will be spread across the European Region and will not be a considered a single point source.

As laboratory use is widespread with a large number of very small point sources the exact tonnage used is difficult to establish. However the amount present on each local source would be less than 1kg by definition. A worst case assumption based on wide dispersive use would be that there are 20 such small sites in a region, each using 5% of the regional tonnage. By default a region has 20000000 inhabitants. Each STP catchment has 10000. Therefore, there are 2000 STPs per region. Therefore assuming even distribution of the 20 laboratories (which is an assumption that fits with the wide dispersive nature of the use) it is unlikely that a single STP catchment will contain more than one laboratory and emissions can be determined on this basis. This is still very much a worst case assumption as the amount emitted by any single laboratory will still be vastly in excess of the 1kg which can be located on one site by definition of the ES.

Table 164: EUSES inputs

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	148.1156	g/mol	
Vapour Pressure	0.0006	hPa	
Water Solubility	11,200 (average of range)	mg/L	
Octanol/water partition coefficient	1.60	logKow	
Koc	10.84 (estimated)		
Biodegradability	Readily Biodegradable		
Life Cycle Step	Production		
Tonnage	EU tonnage :5000 Regional tonnage:500	Tonnes	Regional tonnage based on the 10% rule.
Environmental Release Class	ERC 8A and 8B		
Fraction of Tonnage for Region			1
Fraction of the main local source	0.05		Based on 20 small point sources within each region.
STP			Yes
Emission events per year	300	Days	300 (based on wide dispersive use in laboratories)
Default Release to Air	ERC 8A: 100 ERC 8B: 0.1	%	ERC 8A: 100 ERC 8B: 0.1
Default Release to Water	ERC 8A: 100 ERC 8B: 2	%	ERC 8A: 100 ERC 8B:2
Dilution factor applied for PEC derivation			$25 \times 10^9 \text{ m}^3/\text{a}$ (wide dispersive use)
Estimated number of small point sources in Europe for local and regional assessment	200		Not specified (worst case assumption based on tonnage and on site amounts).

For the tier 1 assessment of environmental releases the release estimation was based on the tonnage data and the ERC defaults.

Table 165 Predicted Releases to the Environment Tier 1

ERC	Compartments	Predicted releases	Measured release	Explanation / source of measured data
8A	Release to water	88.3kg/d	-	Predicted values are those calculated by EUSES using the tonnage data and defaults for ERC8A.
	Release to air	88.3 kg/d	-	Predicted values are those calculated by EUSES using the tonnage data and defaults for ERC8A.
	Soil (direct only) Agricultural soil	0 kd/d	-	No directly loss to soil is expected for this ERC
8B	Release to water	1.67kg/d	-	Predicted values are those calculated by EUSES using the tonnage data and defaults for ERC8B.
	Release to air	0.083 kg/d	-	Predicted values are those calculated by EUSES using the tonnage data and defaults for ERC8B.
	Soil (direct only) Agricultural soil	0 kd/d	-	No directly loss to soil is expected for this ERC

*The predicted releases were estimated using the EUSES 2.1 program.

Tier 2 assessment was not required.

9.5.2.4.1 Exposure concentration in sewage treatment plants (STP)

On contact with water, phthalic anhydride is converted to phthalic acid. Therefore the PEC values presented are essentially those for phthalic acid. As the two substances are considered to be suitable for read across purposes, the PECs and PNECs can be considered equivalent. Phthalic anhydride is produced on a large scale, generally on major chemical sites, with dedicated effluent treatment facilities, involving both chemical and biological treatment, coping with many chemical substances. Biodegradation and microbiological toxicity tests have shown that phthalic anhydride (or phthalic acid) is not toxic to microorganisms and is biodegradable. Disposal of sewage sludge is either by controlled high temperature incineration or to landfill. The model appears to predict 87% removal by STP. However actual measured data indicate at least 99.5% removal by STP and the assumptions used in assessing waste removal levels are therefore worst case. Laboratory waste may be treated on site or sent to the municipal STP and the removal rates above cover both of these scenarios.

Table 166: Tier 1 Concentrations in sewage

ERC	ERC for Compartment:	Estimated exposure concentrations		Measured exposure concentrations*		Explanation / source of measured data
		value	unit	value	unit	
8A	Waste water before treatment	34.7	mg/L	-	mg/L	
	Sewage (STP effluent)	4.39	mg/L		mg/L	
	Sludge	89.9	mg/kg			
	Local freshwater	0.0012	mg/L		mg/L	Based on wide dispersive flow rate
8B	Waste water before treatment	0.0833	mg/L	-	mg/L	
	Sewage (STP effluent)	0.105	mg/L		mg/L	
	Sludge	2.16	mg/kg			
	Local freshwater	0.00003	mg/L		mg/L	Based on wide dispersive flow rate

Table 167: Conservative emission fractions from the STP

Fraction description	Fraction amount	
	value	unit
Fraction of emission directed to air by STP	0.000138	%
Fraction of emission directed to water by STP	12.6	%
Fraction of emission directed to sludge by STP	0.0102	%
Fraction of emission degraded by STP	87.3	%

9.5.2.4.2 Exposure concentration in the aquatic pelagic compartment

Table 168: Tier 1 Local Concentrations in aquatic compartment

ERC	Compartments	PEC aquatic (local mg/L)	Justification
8A	Freshwater (in mg/l)	0.00128	
	Marine water (in mg/l)	0.00126	Wide dispersive dilution
	Intermittent releases to water (in mg/l)	Not relevant	
8B	Freshwater (in mg/l)	3.08×10^{-5}	
	Marine water (in mg/l)	3.07×10^{-5}	Wide dispersive dilution
	Intermittent releases to water (in mg/l)	Not relevant	

Table 169: Tier 1 Predicted Exposure Concentrations (PEC) in aquatic compartment

ERC	Compartments	PEC aquatic (local mg/L)	Justification
8A	Freshwater (in mg/l)	0.0016	
	Marine water (in mg/l)	0.0013	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/l)	Not relevant	
8B	Freshwater (in mg/l)	3.86×10^{-5}	
	Marine water (in mg/l)	2.56×10^{-5}	Wide dispersive dilution
	Intermittent releases to water (in mg/l)	Not relevant	

9.5.2.4.3 Exposure concentration in sediments

Phthalic anhydride (phthalic acid) has been measured in receiving waters at levels <0.1 mg/L. It is biodegradable, and it can be anticipated that it will be degraded either in the water column, or in the upper aerobic layers of any sediment. Phthalic anhydride and its hydrolysis product phthalic acid have a log K_{ow} of 1.6 and 0.73, respectively. These values indicate that both substances have a low adsorption potential on sediments (see 7.1). The weight of evidence strongly indicates that phthalic acid will not accumulate in sediments. Nevertheless PEC_{sediment} values as calculated by EUSES are presented below. The tier 2 predicted environmental concentrations in sediment are extremely low and suggest that the risk to sediment dwelling organisms from use of Phthalic Anhydride in the laboratory is likely to be negligible.

Table 170: Tier 1 Local Concentrations in aquatic sediment compartment

ERC	Compartments	Concentration
8A	Freshwater sediment (in mg/kg wwt)	0.0016
	Marine sediment (in mg/kg wwt)	0.0013
8B	Freshwater sediment (in mg/kg wwt)	3.93×10^{-5}
	Marine sediment (in mg/kg wwt)	3.16×10^{-5}

Table 171: Tier 1 Predicted Exposure Concentrations (PEC) in aquatic sediment compartment

ERC	Compartments	Concentration
8A	Freshwater sediment (in mg/kg wwt)	0.0016
	Marine sediment (in mg/kg wwt)	0.0013
8B	Freshwater sediment (in mg/kg wwt)	3.93×10^{-5}
	Marine sediment (in mg/kg wwt)	3.16×10^{-5}

These predictions do not take into account the biodegradable nature of phthalic acid, and should therefore be regarded as worst-case.

9.5.2.4.4 Exposure concentrations in soil and groundwater

There is no direct disposal of phthalic anhydride to soil under the assumptions of this ERC. However as there may be emissions to the municipal STP emissions to soil via sludge spreading cannot be ruled out and are considered below in a worst case local assessment. Any phthalic anhydride in the atmosphere will be converted to phthalic acid on contact with atmospheric moisture, and any phthalic acid in rainfall will degrade rapidly on contact with soil, however atmospheric deposition is also taken into account in the PEC derivation below. Nonetheless calculated PECs for soil and groundwater are presented below.

Table 172: Tier 1 Local Concentrations in the soil and groundwater compartment

ERC	Compartments	Concentration
8A	Agricultural soil (averaged over 30 days (in mg/kg))	0.0933
	Groundwater (in mg/l)	0.103
8B	Agricultural soil (averaged over 30 days (in mg/kg))	0.004
	Groundwater (in mg/l)	0.008

Table 173: Tier 1 Predicted Exposure Concentrations (PEC) in the soil and groundwater compartment

ERC	Compartments	Concentration
8A	Agricultural soil (averaged over 30 days (in mg/kg))	0.0952
	Groundwater (in mg/l)	0.103
8B	Agricultural soil (averaged over 30 days (in mg/kg))	0.004
	Groundwater (in mg/l)	0.008

These predicted values should be assessed in the light of the above statement on sewage sludge, and the information on atmospheric compartment below.

9.5.2.4.5 Atmospheric compartment

Depending on the size and scale of the laboratory there may be waste gas treatment or capture. However gas removal has not been taken into account here and the below PECs should be considered worst case.

Table 174: Tier 1 local concentrations in air

ERC		Estimated local exposure concentrations	Explanation / source of data
8A	During emission (mg/m ³)	0.0193	Estimated using EUSES 2.1
	Annual average (mg/m ³)	0.019	Estimated using EUSES 2.1
	Annual deposition (mg/m ² /d)	0.0349	Estimated using EUSES 2.1
8B	During emission (mg/m ³)	2.32 x 10 ⁻⁵	Estimated using EUSES 2.1
	Annual average (mg/m ³)	1.9 x 10 ⁻⁵	Estimated using EUSES 2.1
	Annual deposition (mg/m ² /d)	3.44 x 10 ⁻⁵	Estimated using EUSES 2.1

Table 175: Tier 1 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
8A	Annual average PEC in air, total (mg/m ³)	0.019	0.019	Estimated using EUSES 2.1.
8B	Annual average PEC in air, total (mg/m ³)	1.9 x 10 ⁻⁵	1.9 x 10 ⁻⁵	Estimated using EUSES 2.1.

9.5.2.4.6 Exposure concentration relevant for the food chain (Secondary poisoning)

Phthalic anhydride is readily biodegradable in atmospheric, aquatic and soil compartments, and does not bioaccumulate. Removal by STP is effective. Therefore it is considered unlikely that humans will be exposed indirectly either by way of direct contact with the air, surface waters or soils, or by way of drinking water, or through exposure in the food chain.

9.5.2.4.7 Regional exposure levels and environmental concentrations.

Phthalic anhydride may be produced at several sites throughout a region and this may lead to a degree of regional exposure. Regional exposure has been modelled for the production of Phthalic anhydride using the regional module of EUSES 2.1. No significant PEC values are indicated for the regional scale even under the conservative assumptions of the Tier 2 EUSES assessment.

Table 176: Regional concentrations in the environment

ERC8A	Predicted regional Exposure Concentrations		Measured regional exposure concentrations		Explanation / source of measured data
	PEC value	unit	Measured value	unit	
Freshwater	0.000034	mg/l	NA	mg/l	
Marine water	3.7 x 10 ⁻⁶	mg/l	NA	mg/l	
Freshwater sediments	0.0003	mg/kg	NA	mg/kg	
Marine sediments	0.00037	mg/kg	NA	mg/kg	
Agricultural soil	0.0092	mg/kg	NA	mg/kg	
Grassland	0.0019	mg/kg	NA	mg/kg	
Air	7.21 x 10 ⁻⁷	mg/m ³	NA	mg/m ³	

ERC8B	Predicted regional Exposure Concentrations		Measured regional exposure concentrations		Explanation / source of measured data
	PEC value	unit	Measured value	unit	
Freshwater	7.84×10^{-6}	mg/l	NA	mg/l	
Marine water	3.26×10^{-7}	mg/l	NA	mg/l	
Freshwater sediments	6.97×10^{-6}	mg/kg	NA	mg/kg	
Marine sediments	2.93×10^{-7}	mg/kg	NA	mg/kg	
Agricultural soil	8.78×10^{-4}	mg/kg	NA	mg/kg	
Grassland	1.89×10^{-3}	mg/kg	NA	mg/kg	
Air	7.21×10^{-7}	mg/m ³	NA	mg/m ³	