

## Scheda di dati di sicurezza

ai sensi del regolamento 1907/2006/CE, Articolo 31

Stampato il: 09.01.2023

Numero versione 7.0 (sostituisce la versione 6.3)

Revisione: 20.12.2022

### SEZIONE 1: Identificazione della sostanza/miscela e della società/impresa

#### - 1.1 Identificatore del prodotto

- **Denominazione commerciale:** Potassio idrato gocce USP

- **Articolo numero:** 1663-10301527

- **Numero CAS:**

1310-58-3

- **Numeri CE:**

215-181-3

- **Numero indice:**

19-002-00-8

- **Numero di registrazione** 01-2119487136-33-0006

- **1.2 Usi identificati pertinenti della sostanza o della miscela e usi sconsigliati**

- **Settore d'uso**

SU1 Agricoltura, silvicoltura, pesca

SU2a Attività minerarie (tranne le industrie offshore)

SU2b Industrie offshore

SU5 Confezione di articoli in tessuto, pelle e pelliccia

SU6a Lavorazione di legno e prodotti in legno

SU6b Produzione di pasta per la fabbricazione della carta, carta e prodotti di carta

SU7 Stampa e riproduzione di supporti registrati

SU8 Produzione di prodotti chimici di base su larga scala (compresi i prodotti petroliferi)

SU9 Fabbricazione di prodotti di chimica fine

SU10 Formulazione [miscelazione] di preparati e/o reimballaggio (tranne le leghe)

SU11 Fabbricazione di articoli in gomma

SU12 Fabbricazione di materie plastiche, compresa la miscelazione (compounding) e la conversione

SU13 Fabbricazione di altri prodotti della lavorazione di minerali non metalliferi, per esempio intonaci, cemento

SU14 Attività metallurgiche, comprese le leghe

SU15 Fabbricazione di prodotti in metallo, esclusi macchinari e attrezzature

SU16 Fabbricazione di computer e prodotti di elettronica e ottica, apparecchiature elettriche

SU18 Fabbricazione di mobili

SU17 Fabbricazione di macchine di impiego generale, ad esempio macchinari, apparecchiature, veicoli e altri mezzi di trasporto

SU19 Costruzioni

SU20 Servizi sanitari

SU23 Elettricità, vapore, gas, fornitura di acqua e trattamento delle acque reflue

SU24 Ricerca e sviluppo scientifici

#### - **Categoria dei prodotti**

PC1 Adesivi, sigillanti

PC2 Assorbenti

PC3 Depuratori dell'aria

PC4 Prodotti antigelo e prodotti per lo sbrinamento

PC7 Metalli di prima trasformazione e leghe

PC8 Biocidi

PC9a Rivestimenti e vernici, diluenti, sverniciatori

PC9b Additivi, stucchi, intonaci, argilla da modellare

PC9c Colori a dita

PC11 Esplosivi

PC12 Fertilizzanti

PC13 Combustibili

PC14 Prodotti per il trattamento di superfici metalliche

PC15 Prodotti per il trattamento delle superfici non metalliche

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- PC16 Fluidi per il trasferimento di calore
- PC17 Liquidi idraulici
- PC18 Inchiostri e toner
- PC19 Sostanze intermedie
- PC20 Coadiuvanti tecnologici quali regolatori di pH, flocculanti, precipitatori, agenti neutralizzanti
- PC21 Sostanze chimiche da laboratorio
- PC23 Prodotti per il trattamento delle pelli
- PC24 Lubrificanti, grassi e prodotti di rilascio
- PC25 Liquidi per la lavorazione dei metalli
- PC26 Prodotti per il trattamento di carta e cartone
- PC27 Prodotti fitosanitari
- PC28 Profumi, fragranze
- PC29 Prodotti farmaceutici
- PC30 Prodotti fotochimici
- PC31 Lucidanti e miscele di cera
- PC32 Preparati e composti polimerici
- PC33 Semiconduttori
- PC34 Coloranti e prodotti per l'impregnazione di materie tessili
- PC35 Prodotti per il lavaggio e la pulizia (tra cui prodotti a base di solventi)
- PC36 Depuratori d'acqua
- PC37 Prodotti chimici per il trattamento delle acque
- PC38 Prodotti per la saldatura e la brasatura, prodotti flussanti
- PC39 Cosmetici, prodotti per la cura personale
- PC40 Agenti per l'estrazione

**- Categoria dei processi**

- PROC1 Produzione o raffinazione di sostanze chimiche in processi chiusi, senza possibilità di esposizione o in processi con condizioni di contenimento equivalenti
- PROC2 Produzione o raffinazione di sostanze chimiche in un processo chiuso e continuo, con occasionale esposizione controllata o processi con condizioni di contenimento equivalenti
- PROC3 Fabbricazione o formulazione di sostanze chimiche in processi a lotti chiusi, con occasionale esposizione controllata o processi con condizioni di contenimento equivalenti
- PROC4 Produzione di sostanze chimiche con possibilità di esposizione
- PROC5 Miscelazione o mescolamento in processi a lotti
- PROC7 Applicazioni a spruzzo industriali
- PROC8a Trasferimento di una sostanza o di un preparato (riempimento/svuotamento) presso strutture non dedicate
- PROC8b Trasferimento di una sostanza o di una miscela (riempimento/svuotamento) presso strutture dedicate
- PROC9 Trasferimento di una sostanza o di un preparato in piccoli contenitori (linea di riempimento dedicata, compresa la pesatura)
- PROC10 Applicazione con rulli o pennelli
- PROC11 Applicazioni a spruzzo non industriali
- PROC13 Trattamento di articoli per immersione e colata
- PROC14 Pastigliatura, compressione, estrusione, pelletizzazione, granulazione
- PROC15 Uso come reagenti per laboratorio
- PROC19 Attività manuali con contatto diretto
- PROC23 Operazioni di lavorazione e trasferimento nell'ambito di processi aperti, a temperature notevolmente elevate
- PROC24 Lavorazione in condizioni meccaniche gravose di sostanze incorporate o di rivestimento in materiali e/o articoli
- PROC26 Manipolazione di sostanze inorganiche solide a temperatura ambiente

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**- Categoria rilascio nell'ambiente**

- ERC1 Fabbricazione della sostanza
- ERC2 Formulazione di miscele
- ERC4 Uso industriale di coadiuvanti tecnologici non reattivi (senza inclusione all'interno o sulla superficie dell'articolo)
- ERC5 Uso industriale con conseguente inclusione all'interno o sulla superficie di un articolo
- ERC6a Uso di sostanze intermedie
- ERC6b Uso industriale di coadiuvanti tecnologici reattivi (senza inclusione all'interno o sulla superficie dell'articolo)
- ERC7 Uso industriale di fluidi funzionali
- ERC8a Uso generalizzato di coadiuvanti tecnologici non reattivi (senza inclusione all'interno o sulla superficie di un articolo, uso in interni)
- ERC8b Uso generalizzato di coadiuvanti tecnologici reattivi (senza inclusione all'interno o sulla superficie di un articolo, uso in interni)
- ERC8c Uso generalizzato con conseguente inclusione all'interno o sulla superficie di un articolo (uso in interni)
- ERC8d Uso generalizzato di coadiuvanti tecnologici non reattivi (senza inclusione all'interno o sulla superficie di un articolo, uso in esterni)
- ERC8e Uso generalizzato di coadiuvanti tecnologici reattivi (senza inclusione all'interno o sulla superficie di un articolo, uso in esterni)
- ERC8f Uso generalizzato con conseguente inclusione all'interno o sulla superficie di un articolo (uso in esterni)
- ERC9a Uso generalizzato di fluidi funzionali (uso in interni)
- ERC9b Uso generalizzato di fluidi funzionali (in esterni)

**- Categoria degli articoli AC3 Batterie elettriche e accumulatori**
**- Utilizzazione della Sostanza / del Preparato** Intermediario chimico

**- 1.3 Informazioni sul fornitore della scheda di dati di sicurezza**
**- Produttore/fornitore:**

Vynova PPC SAS  
 95, Rue du Général de Gaulle B.P. 60090  
 68802 Thann CECEX - France  
 Tel : +33 (0)3 89 38 46 00



Fornito da:

**ANDREA GALLO DI LUIGI S.r.l.u.**
*Azienda fondata nel 1892*

 Via Erzelli 9, 16152 Genova, Italy Tel. +39 (0)10 6502941  
[www.andreagallo.it](http://www.andreagallo.it)
**- Informazioni fornite da:**

Département SHEQ  
 vytha.fdsinfo@vynova-group.com

**- 1.4 Numero telefonico di emergenza:** CARECHEM 24: +33 3 89 38 46 88 - 24h / 24h

**- Centro nazionale antiveleno**

I: +390.2.661.01.029 (Centro antiveleni - Ospedale Niguarda ca' granda)  
 CH: +41.(0)1.251.51.51 (Centre suisse d'information toxicologique)

### SEZIONE 2: Identificazione dei pericoli

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


GHS05 corrosione

Met. Corr.1 H290 Può essere corrosivo per i metalli.

Skin Corr. 1A H314 Provoca gravi ustioni cutanee e gravi lesioni oculari.

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GHS07

Acute Tox. 4 H302 Nocivo se ingerito.

### - 2.2 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

#### - Avvertenza Pericolo

#### - Indicazioni di pericolo

H290 Può essere corrosivo per i metalli.

H302 Nocivo se ingerito.

H314 Provoca gravi ustioni cutanee e gravi lesioni oculari.

#### - Consigli di prudenza

P260 Non respirare la polvere/i fumi/i gas/la nebbia/i vapori/gli aerosol.

P280 Indossare guanti/indumenti protettivi/proteggere gli occhi/proteggere il viso.

P303+P361+P353 IN CASO DI CONTATTO CON LA PELLE (o con i capelli): togliersi di dosso immediatamente tutti gli indumenti contaminati. Sciacquare la pelle.

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.

P310 Contattare immediatamente un CENTRO ANTIVELENI/un medico.

#### - 2.3 Altri pericoli Nessun altro rischio noti

#### - Risultati della valutazione PBT e vPvB

##### - PBT:

La sostanza non soddisfa i criteri PBT di classificazione di cui all'allegato XIII del regolamento (CE) 1907/2006

##### - vPvB:

La sostanza non soddisfa i criteri di classificazione per la classificazione vPvB secondo l'allegato XIII del regolamento (CE) 1907/2006

## SEZIONE 3: Composizione/informazioni sugli ingredienti

### - 3.1 Sostanze

#### - Numero CAS

1310-58-3 Idrossido di potassio

#### - Numero/i di identificazione

- Numeri CE: 215-181-3

- Numero indice: 019-002-00-8

#### - Ulteriori indicazioni:

Flakes or Pellets

≥ 85 %

- Formula Chimica KOH

- Massa molecolare 56,105 g/mol

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**- Limiti di concentrazione specifici**

Skin Corr. 1A; H314:  $C \geq 5\%$   
Skin Corr. 1B; H314:  $2\% \leq C < 5\%$   
Skin Irrit. 2; H315:  $0,5\% \leq C < 2\%$   
Eye Irrit. 2; H319:  $0,5\% \leq C < 2\%$

**SEZIONE 4: Misure di primo soccorso****- 4.1 Descrizione delle misure di primo soccorso**

Per chi interviene direttamente: Usare la protezione personale raccomandata nella sezione 8

**- Indicazioni generali:**

Allontanare immediatamente gli abiti contaminati dal prodotto.  
Portare le persone da soccorrere all'aria aperta.  
Consultare immediatamente il medico.

**- Inalazione:**

Se il soggetto è svenuto provvedere a tenerlo durante il trasporto in posizione stabile su un fianco.  
In caso di affanno praticare la terapia con ossigeno.  
Caso di arresto respiratorio, praticare la respirazione artificiale.

**- Contatto con la pelle:**

Può provocare bruciate ritardate.  
In caso di contatto con la pelle lavarsi immediatamente ed abbondantemente almeno 15 minuti con acqua.

**- Contatto con gli occhi:** Lavare con acqua corrente almeno 15 minuti tenendo le palpebre ben aperte.

**- Ingestione:**

Chiamare subito il medico.  
Sclacquare bene la bocca con acqua.

**- 4.2 Principali sintomi ed effetti, sia acuti che ritardati**

Per ulteriori informazioni sulle conseguenze in termini di salute, fare riferimento alla Sezione 11

**- 4.3 Indicazione dell'eventuale necessità di consultare immediatamente un medico e di trattamenti speciali**

Non sono disponibili altre informazioni.

**- Attrezzatura di emergenza**

Provvede impianti di lavaggio per gli occhi e per la pelle in prossimità delle zone di lavoro.

**SEZIONE 5: Misure di lotta antincendio****- 5.1 Mezzi di estinzione****- Mezzi di estinzione idonei:**

Anidride carbonica, prodotti chimici secchi, schiume, polverizzazioni di acqua (nebbia).  
Adottare provvedimenti antincendio nei dintorni della zona colpita.

**- 5.2 Pericoli speciali derivanti dalla sostanza o dalla miscela**

Può, a temperature elevate, sprigionare gas tossici od corrosivi. Non respirare il fumo od i vapori.

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

Raffreddare, con mezzi adeguati, i contenitori esposti al calore.  
Arginare e contenere liquidi estinguenti.

**- Mezzi protettivi specifici:**

Portare un respiratore ad alimentazione autonoma.

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Indossare tute protettive integrali.

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### SEZIONE 6: Misure in caso di rilascio accidentale

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

Evitare il contatto con la pelle.  
Evitare il contatto con gli occhi.  
Indossare il respiratore.

Indossare equipaggiamento protettivo. Allontanare le persone non equipaggiate.

Per chi interviene direttamente: Usare la protezione personale raccomandata nella sezione 8

**- 6.2 Precauzioni ambientali:**

Impedire l'entrata del prodotto nelle fognature o nei corpi d'acqua.  
Impedire infiltrazioni nella fognatura/nelle acque superficiali/nelle acque freatiche.

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

Neutralizzare con acido soluzione e lavare abbondantemente.  
Utilizzare mezzi di neutralizzazione.

Smaltimento del materiale contaminato conformemente al punto 13.

Raccogliere con mezzi meccanici.

Provvedere ad una sufficiente areazione.

Può essere necessaria l'evacuazione del terreno contaminato. Spazzare via i residui e preparare un contenitore sigillabile contrassegnato per una sistemazione sicura. Porre i contenitori che perdono in un fusto.

Metodi di contenimento: Contenere la fuoriuscita o perdita se può essere fatto in modo sicuro.

**- 6.4 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.

### SEZIONE 7: Manipolazione e immagazzinamento

**- 7.1 Precauzioni per la manipolazione sicura**

In caso di formazione di polvere procedere all'aspirazione.

Accurata captazione delle polveri.

Da manipolare conformandosi alla normale igiene industriale ed alle normali procedure di sicurezza.

**- Indicazioni in caso di incendio ed esplosione:** Non sono richiesti provvedimenti particolari.

**- 7.2 Condizioni per lo stoccaggio sicuro, comprese eventuali incompatibilità****- Stoccaggio:****- Requisiti dei magazzini e dei recipienti:**

Conservare solo all'interno dei fusti originali ancora chiusi.

Conservare in un luogo secco, fresco e ben ventilato.

**- Indicazioni sullo stoccaggio misto:** Non necessario.

**- Ulteriori indicazioni relative alle condizioni di immagazzinamento:**

Proteggere da umidità e acqua.

Mantenere i recipienti ermeticamente chiusi.

**- 7.3 Usi finali particolari** Non sono disponibili altre informazioni.

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### SEZIONE 8: Controlli dell'esposizione/della protezione individuale

#### - 8.1 Parametri di controllo

- **Componenti i cui valori limite devono essere tenuti sotto controllo negli ambienti di lavoro:**

##### **1310-58-3 Idrossido di potassio**

TWA (Italia)	Limite Ceiling: 2 mg/m <sup>3</sup>
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- **Informazioni sulla regolamentazione TWA (Italia):** Valori Limite di Soglia

#### - DNEL

Per inalazione	DNEL Local/Acute/long term exposure	1 mg/m <sup>3</sup> (Workers)
	DNEL (Long-term / Local effects)	1 mg/m <sup>3</sup> (Population)

- **Ulteriori indicazioni:** Le liste valide alla data di compilazione sono state usate come base.

#### - 8.2 Controlli dell'esposizione

- **Controlli tecnici idonei** Nessun dato ulteriore, vedere punto 7.

- **Misure di protezione individuale, quali dispositivi di protezione individuale**

- **Norme generali protettive e di igiene del lavoro:**

Osservare le misure di sicurezza usuali nella manipolazione di sostanze chimiche.

Tenere lontano da cibo, bevande e foraggi.

Togliere immediatamente gli abiti contaminati.

Lavarsi le mani prima dell'intervallo o a lavoro terminato.

Evitare il contatto con gli occhi e la pelle.

- **Protezione respiratoria**



In caso di emissione di polvere o aerosol, utilizzare una protezione respiratoria filtrante (Filtro consigliato: Tipo P2)

- **Protezione delle mani**



Guanti protettivi

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.

- **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.

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

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

- **Per il contatto continuo sono adatti dei guanti costituiti dai materiali seguenti:**

Materiale dei guanti : PVC

Spessore : 1.35 mm

Tempo di passaggio : > 480'

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**- Protezione degli occhi/del volto**


Occhiali protettivi a tenuta

**- Tuta protettiva:**

Indossare la tuta protettiva.

L'equipaggiamento personale per il corpo deve essere selezionato in base al compito svolto ed al rischio previsto. Si raccomanda di essere approvati da personale qualificato prima dell'uso.

**- Controlli dell'esposizione ambientale**

Emissioni atmosferiche dovrebbero essere trattati dai sistemi di purificazione e controllati secondo le caratteristiche del prodotto. (COV, acidità, Altro).

Emissioni atmosferiche dovrebbero essere trattati dai sistemi di purificazione e controllati secondo le caratteristiche del prodotto. (COV, acidità, Altro).

### \* SEZIONE 9: Proprietà fisiche e chimiche

**- 9.1 Informazioni sulle proprietà fisiche e chimiche fondamentali**
**- Indicazioni generali**
**- Stato fisico**

Solido

**- Colore:**

Bianco

**- Odore:**

Inodore

**Soglia olfattiva:**

Non definito.

**- Punto di fusione/punto di congelamento:**

406 °C (Handbook)

**- Punto di ebollizione o punto di ebollizione iniziale e intervallo di ebollizione**

1327 °C (Handbook)

**- Infiammabilità**

Sostanza non infiammabile.

**- Limite di esplosività inferiore e superiore**
**Inferiore:**

Non definito.

**Superiore:**

Non definito.

**- Punto di infiammabilità:**

Non applicabile.

**Temperatura di accensione:**

Non definito.

**- Temperatura di decomposizione:**

Non definito.

**- pH**

ca 13.5 at 5.611 g/l &amp; 25°C (Merck Index)

**- Viscosità:**
**- Viscosità cinematica**

Non applicabile.

**- Tensione superficiale :**
**- Dinamica:**

Non applicabile.

**- Solubilità**
**in acqua a 20 °C:**

1120 g/l (CRC Handbook)

**- Coefficiente di ripartizione n-ottanolo/acqua (valore logaritmico)**

Non definito.

**Stabilità della dispersione :**
**- Tensione di vapore:**

Non applicabile.

**- Densità e/o densità relativa :**
**Densità a 20 °C:**

 2,04 g/cm<sup>3</sup> (Bibliography)

**Densità relativa :**

Non definito.

**- Densità di vapore:**

Non applicabile.

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- <b>Caratteristiche delle particelle</b>	Nessuna particella < 100 µm (Pellets / Flakes)
<b>- 9.2 Altre informazioni</b>	
- <b>Aspetto:</b>	
<b>Forma:</b>	Solido
- <b>Informazioni importanti sulla protezione della salute e dell'ambiente nonché della sicurezza</b>	
- <b>Temperatura di autoaccensione:</b>	Non definito.
<b>Proprietà esplosive:</b>	Prodotto non esplosivo.
- <b>Formula bruta</b>	KOH
- <b>Peso molecolare</b>	56,105 g/mol
- <b>Cambiamento di stato punto/l'intervallo di rammollimento</b>	Non definito.
- <b>Proprietà ossidanti:</b>	Non comburente
- <b>Velocità di evaporazione</b>	Non applicabile.
<b>- Informazioni relative alle classi di pericoli fisici</b>	
<b>Esplosivi</b>	non applicabile
<b>Gas infiammabili</b>	non applicabile
<b>Aerosol</b>	non applicabile
<b>Gas comburenti</b>	non applicabile
<b>Gas sotto pressione</b>	non applicabile
<b>Liquidi infiammabili</b>	non applicabile
<b>Solidi infiammabili</b>	non applicabile
<b>Sostanze e miscele autoreattive</b>	non applicabile
<b>Liquidi piroforici</b>	non applicabile
<b>Solidi piroforici</b>	non applicabile
<b>Sostanze e miscele autoriscaldanti</b>	non applicabile
<b>Sostanze e miscele che emettono gas infiammabili a contatto con l'acqua</b>	non applicabile
<b>Liquidi comburenti</b>	non applicabile
<b>Solidi comburenti</b>	non applicabile
<b>Perossidi organici</b>	non applicabile
<b>Sostanze o miscele corrosive per i metalli</b>	Può essere corrosivo per i metalli.
<b>Esplosivi desensibilizzati</b>	non applicabile
- <b>Altre caratteristiche di sicurezza</b>	Non sono disponibili altre informazioni.

### SEZIONE 10: Stabilità e reattività

- **10.1 Reattività** Non sono disponibili altre informazioni.
- **10.2 Stabilità chimica**
- **Decomposizione termica/ condizioni da evitare:** Stabile in condizioni normali di utilizzo.
- **10.3 Possibilità di reazioni pericolose**
- Reazione con acqua e acidi.
- In caso di aggiunta di acqua si verifica un riscaldamento.
- Reazioni con acidi forti e ossidanti.
- Il contatto con rame, l'alluminio, lo stagno o lo zinco può provocare la formazione di gas idrogeno infiammabile.
- **10.4 Condizioni da evitare** Non sono disponibili altre informazioni.
- **10.5 Materiali incompatibili:**
- Evitare etere.

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Evitare materia organica.

Evitare il contatto con Al, Zn, Sn, Cu e leghe di Al, Zn, Sn, Cu.

**- 10.6 Prodotti di decomposizione pericolosi:** Monossido di carbonio e anidride carbonica

### SEZIONE 11: Informazioni tossicologiche

**- 11.1 Informazioni sulle classi di pericolo definite nel regolamento (CE) n. 1272/2008**
**- Tossicità acuta** Nocivo se ingerito.

**- Valori LD/LC50 rilevanti per la classificazione:**

Orale	LD50	333 mg/kg (Rat) (OECD 425_Acute Oral Toxicity)
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**- Corrosione cutanea/irritazione cutanea**

Corrosivo (OECD TG 431\_Skin corrosion - In vitro)

Provoca gravi ustioni cutanee e gravi lesioni oculari.

**- Gravi danni oculari/irritazione oculare** Corrosivo (OECD 405\_Acute Eye irritation / Corrosion)

**- Sensibilizzazione respiratoria o cutanea**

Non sensibilizzante (Publication)

Basandosi sui dati disponibili i criteri di classificazione non sono soddisfatti.

**- Mutagenicità sulle cellule germinali**

Prova negativa (In vitro\_Test Ames-Publication)

Basandosi sui dati disponibili i criteri di classificazione non sono soddisfatti.

**- Cancerogenicità** Basandosi sui dati disponibili i criteri di classificazione non sono soddisfatti.

**- Tossicità per la riproduzione** Basandosi sui dati disponibili i criteri di classificazione non sono soddisfatti.

**- Tossicità specifica per organi bersaglio (STOT) - esposizione singola**

Basandosi sui dati disponibili i criteri di classificazione non sono soddisfatti.

**- Tossicità specifica per organi bersaglio (STOT) - esposizione ripetuta**

Basandosi sui dati disponibili i criteri di classificazione non sono soddisfatti.

**- Pericolo in caso di aspirazione** Basandosi sui dati disponibili i criteri di classificazione non sono soddisfatti.

**- Ulteriori dati tossicologici:**
**- Effetti acuti (tossicità acuta, irritazione e corrosività)**

Provoca ustioni.

Rischio di gravi lesioni oculari.

Nocivo per ingestione.

**- Informazioni sulle vie probabili di esposizione** Mancanza di informazioni

**- Sintomi connessi alle caratteristiche fisiche, chimiche e tossicologiche** Non conosciuto

**- Effetti immediati e ritardati ed effetti cronici derivanti da esposizioni a breve e a lungo termine** Non conosciuto

**- Effetti interattivi** Non conosciuto

**- 11.2 Informazioni su altri pericoli**
**- Proprietà di interferenza con il sistema endocrino** La sostanza non è contenuta

### SEZIONE 12: Informazioni ecologiche

**- 12.1 Tossicità**
**- Tossicità acquatica:**

LC50/96h	50-165 mg/l (Piscis) (Publication)
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**- 12.2 Persistenza e degradabilità** Non applicabile.

**- Comportamento in compartimenti ecologici:** Nessun dato.

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**- 12.3 Potenziale di bioaccumulo**

Nessun dato.

Non sono disponibili altre informazioni.

**- 12.4 Mobilità nel suolo** Non sono disponibili altre informazioni.

**- 12.5 Risultati della valutazione PBT e vPvB**
**- PBT:** Secondo i risultati della sua valutazione, questa sostanza non è PBT

**- vPvB:** Secondo i risultati della sua valutazione, questa sostanza non vPvB

**- 12.6 Proprietà di interferenza con il sistema endocrino**

Il prodotto non contiene sostanze con proprietà dannose per il sistema endocrinale.

**- 12.7 Altri effetti avversi**
**- Ulteriori indicazioni:**
**- Ulteriori indicazioni:**

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

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

Non immettere il prodotto non diluito o non neutralizzato nelle acque di scarico e nei canali di raccolta.

### SEZIONE 13: considerazioni sullo smaltimento

**- 13.1 Metodi di trattamento dei rifiuti**
**- Consigli:** Non smaltire il prodotto insieme ai rifiuti domestici Non immettere nelle fognature.

**- Catalogo europeo dei rifiuti**

HP6	Tossicità acuta
HP8	Corrosivo

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

**- Detergente consigliato:** Acqua eventualmente con l'aggiunta di detersivi.

### SEZIONE 14: Informazioni sul trasporto

**- 14.1 Numero ONU o numero ID**
**- ADR/RID/ADN, IMDG, IATA** UN1813

**- 14.2 Designazione ufficiale ONU di trasporto**
**- ADR/RID/ADN** 1813 IDROSSIDO DI POTASSIO SOLIDO

**- IMDG, IATA** POTASSIUM HYDROXIDE, SOLID

**- 14.3 Classi di pericolo connesso al trasporto**
**- ADR/RID/ADN**

**- Classe** 8 (C6) Materie corrosive

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- Etichetta	8
- IMDG, IATA	
	
- Class	8 Materie corrosive
- Label	8
- 14.4 Gruppo d'imballaggio	
- ADR/RID/ADN, IMDG, IATA	II
- 14.5 Pericoli per l'ambiente	
	Non applicabile.
- 14.6 Precauzioni speciali per gli utilizzatori	
- N° identificazione pericolo (Numero Kemler):	80
- Numero EMS:	F-A,S-B
- Segregation groups	Alkalis
- Stowage Category	A
- Segregation Code	SG35 Stow "separated from" SGG1-acids
- 14.7 Trasporto marittimo alla rinfusa conformemente agli atti dell'IMO	
	Non applicabile.
- Trasporto/ulteriori indicazioni:	
- ADR/RID/ADN	
- Quantità limitate (LQ)	1 kg
- Quantità esenti (EQ)	Codice: E2 Quantità massima netta per imballaggio interno: 30 g Quantità massima netta per imballaggio esterno: 500 g
- Categoria di trasporto	2
- Codice di restrizione in galleria	E
- IMDG	
- Limited quantities (LQ)	1 kg
- Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 500 g Marpol II: Not determined - Marpol III: Not regulated
- Osservazioni:	
- IATA	
- Osservazioni:	Aircraft Passenger: 15 kg - Aircraft Cargo: 50 kg
- UN "Model Regulation":	
	UN 1813 IDROSSIDO DI POTASSIO SOLIDO, 8, II

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### SEZIONE 15: informazioni sulla regolamentazione

- **15.1 Disposizioni legislative e regolamentari su salute, sicurezza e ambiente specifiche per la sostanza o la miscela**
- **Direttiva 2012/18/UE :**
- **Sostanze pericolose specificate - ALLEGATO I** La sostanza non è contenuta
- **Direttiva 2011/65/UE sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche - Allegato II**  
La sostanza non è contenuta
- **REGOLAMENTO (UE) 2019/1148**
- **Allegato I - PRECURSORI DI ESPLOSIVI SOGGETTI A RESTRIZIONI (Valore limite superiore ai fini della concessione di licenze a norma dell'articolo 5, paragrafo 3)**  
La sostanza non è contenuta
- **Allegato II - PRECURSORI DI ESPLOSIVI SOGGETTI A SEGNALAZIONE** La sostanza non è contenuta
- **Regolamento (CE) n. 273/2004 relativo ai precursori di droghe** La sostanza non è contenuta
- **Regolamento (CE) N. 111/2005 recante norme per il controllo del commercio dei precursori di droghe tra la Comunità e i paesi terzi**  
La sostanza non è contenuta
- **Disposizioni nazionali:**
- **Elenco delle sostanze soggette ad autorizzazione (REACH - Annex XIV) :** La sostanza non è contenuta
- **Products included in the CWC Schedules :** La sostanza non è contenuta
- **Disposizioni europee :**
- **Sostanze che riducono lo strato di ozono** La sostanza non è contenuta
- **Regolamento sui precursori di droghe :** La sostanza non è contenuta
- **Elenco e inventario delle sostanze chimiche :**
- **European Inventory of Existing Commercial chemical Substances (EINECS) :** La sostanza è contenuta
- **European List of Notified Chemicals Substances (ELINCS) :** La sostanza non è contenuta
- **15.2 Valutazione della sicurezza chimica:** Una valutazione della sicurezza chimica è stata effettuata.

### SEZIONE 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.

Le informazioni e le raccomandazioni precedenti sono presentate in buona fede e col presupposto che siano esatte alla data odierna, Vynova PPC SAS, tuttavia, non risponde della loro completezza e precisione. Le informazioni sono fornite a condizione che i riceventi ne guidichino personalmente la sicurezza e l'adeguatezza prima dell'uso del prodotto. In ogni caso la Vynova PPC SAS non risponde di danni di qualsiasi natura derivant dall'uso di tali informazioni. Non esistono garanzie, esplicite o implicite, di commerciabilità e di idoneità a qualsiasi uso particolare o di qualsiasi altra natura, con riferimento alle informazioni od al prodotto a cui queste si riferiscono.

- **Data della versione precedente:** 01.10.2020
- **Numero di versione della versione precedente:** 6.3
- **Abbreviazioni e acronimi:**

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

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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IATA: International Air Transport Association  
GHS: Globally Harmonised 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)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Met. Corr.1: Sostanze o miscele corrosive per i metalli – Categoria 1  
Acute Tox. 4: Tossicità acuta – Categoria 4  
Skin Corr. 1A: Corrosione/irritazione della pelle – Categoria 1A  
- **Fonti** Tutte le fonti di dati sono elencati nella CSR

IT

# Extended Material Safety Data Sheet – Potassium Hydroxide

## 1. EXPOSURE ASSESSMENT

The exposure assessment is organised in several scenarios:

- ES1: Industrial and professional use of KOH
- ES2: Consumer use of KOH in preparations (excl. batteries)
- ES3: Use of KOH in batteries

A separate scenario was developed for use of KOH in batteries because this is the only scenario characterized by an article category with a specific service life and waste stage. The industrial uses (production of alkaline batteries and recovery processes) are covered under the exposure scenario 1 (Industrial and Professional use of KOH). The overview of exposure scenarios and coverage of substance life cycle can be found in Table 1.

The exposure assessment is based on measured data and analogous data from the exposure assessment of the EU RAR for NaOH (2007). KOH and NaOH have an analogous hazardous profile and similar exposure characteristics and comparable activities.

**Table 1: Overview on exposure scenarios and coverage of substance life cycle**

Number and title	Manu- facture	Prepa- ration making	Industrial and/or wide dispersive use	Consumer use	Article service life	Waste stage
ES1: Industrial and professional use of KOH		X	X			
ES2: Consumer use of KOH in preparations (excl. batteries)				X		
ES3: Use of KOH in batteries				X	X	X

# 1.1. Exposure Scenario 1 : Industrial and professional use of solid and liquid KOH

## 1.1.1. Exposure scenario

### 1.1.1.1. Short title of the exposure scenario

The OECD SIAR report (last update Feb 2002) gives an overview of the uses for KOH.

KOH has mainly industrial uses. On a global level the main uses are: production of potassium carbonate (26 %), chemical manufacturing (16 %), production of potassium chemicals (12 %), production of fertilizers (11 %), production of phosphates (9 %), production of detergents (8 %), production of agricultural chemicals (7 %), production of alkaline batteries (6 %), all other (5 %) (OECD SIAR, 2002).

So, more than 95% of the KOH production is for non dispersive use, and is consumed by the industry, mainly by large enterprises. KOH is used in these applications as an intermediate or as a reactive processing aid and does not leave the plant where it is used. In these applications, KOH is consumed in a reaction and is no more present in the product that goes to the market.

KOH is still present in the alkaline batteries, but here this substance is strictly confined in the battery screening and does not come in contact with the consumer.

Less than 5% of the KOH production is for wide dispersive use and enters in the composition of products for professional use or consumer products (eventually to be consumed in small enterprises like garages or farms): paint and varnish removers, drain cleaners (Howell, 1991; Leape et al., 1971), degreasing agents (Swanson et al., 1995) and dairy pipeline cleaners (Edmonson, 1987).

Potassium hydroxide could be used according to the following process categories (PROC):

PROC1	Use in closed process, no likelihood of exposure
PROC2	Use in closed, continuous process with occasional controlled exposure (e.g. sampling)
PROC3	Use in closed batch process (synthesis or formulation)
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5	Mixing or blending in batch processes for formulation of preparations and articles
PROC7	Spraying in industrial settings and applications
PROC8a/b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers
PROC9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC10	Roller application or brushing of adhesive and other coating
PROC11	Spraying outside industrial settings or applications
PROC13	Treatment of articles by dipping and pouring
PROC14	Production of preparations or articles by tableting, compression, extrusion, pelettisation
PROC15	Use a laboratory reagent
PROC19	Hand-mixing with intimate contact and only PPE available
PROC23	Open processing and transfer operations (with minerals) at elevated temperature
PROC24	High (mechanical) energy work-up of substances bound in materials and/or articles
PROC26	Handling of solid inorganic substances at ambient temperature

The process categories mentioned above are assumed to be the most important ones but other process categories could also be possible (PROC 1 – 27).

Potassium hydroxide can be used in many different chemical product categories (PC): Coatings and Paints, Fillers, Putties, Thinners (PC 9), Fertilizers (PC12), Intermediate (PC19), Products such as pH-regulators, flocculants, precipitants, neutralization agents (PC20), Washing and Cleaning Products (PC35), Water treatment chemicals (PC37), Cosmetics (PC39), Extraction agents (PC40). However, it could potentially also be used in other chemical product categories (PC 0 – 40).



Because potassium hydroxide has so many uses and is used so widely it can potentially be used in all sectors of use (SU) described by the use descriptor system (SU 1-23).

The article categories (AC) are not applicable for potassium hydroxide in this exposure scenario.

To assess the environmental exposure of substances environmental release categories (ERC) have been developed for REACH. For potassium hydroxide the following environmental release categories could be applicable:

- ERC2 Formulation of preparations
- ERC4 Industrial use of processing aids
- ERC5 Industrial use resulting in inclusion into or onto a matrix
- ERC6 Industrial use of intermediates and reactive processing aids
- ERC7 Industrial use of substances in closed systems
- ERC8 Wide dispersive indoor and outdoor use of reactive substances, processing aids in open systems

The environmental release categories mentioned above are assumed to be the most important ones but other environmental release categories could also be possible (ERC 1 – 11b).

### **1.1.1.2. Description of activities, processes and operational conditions covered in the exposure scenario**

Potential human exposure to KOH is thus for less than 5% of its total production. Without taking into account recycling of the alkaline batteries (these represent 6 % of the total production), which is normally done in many countries, the potential exposure to the environment is less than 11% of the total production. Losses through production, through processes that use the compound and through disposal of the compound are minimized. The pH of effluents of production sites is controlled and these must be neutralized, this being normally regulated according to local requirements.

#### **1.1.1.2.1. Use of KOH and formulations by industry**

KOH is mainly used as intermediate for the production of organic and inorganic chemicals which end up in a broad variety of end products. At the production sites of organic and inorganic chemicals, KOH is used as pH stabiliser or as reactant for synthesis of other chemicals. In all cases KOH must be added to a reaction vessel and will react after which no KOH is left. In some plants KOH is recycled to the process.

KOH is also used in alkaline batteries. KOH is still present in the alkaline batteries, but here this substance is strictly confined in the battery screening and does not come in contact with the worker/professional/consumer. Recovery of KOH from alkaline batteries includes emptying the electrolyte, collection and neutralization with sulphuric acid and carbon dioxide, optionally including sedimentation step to remove Ni and Cd ions.

#### **1.1.1.2.2. Use of KOH and formulations by professionals**

KOH also has professional uses. This includes following processes/activities: transfer of KOH by professionals and wide dispersive indoor and outdoor use of KOH-containing formulations: detergents, fertilizers, drain cleaners, paint strippers, cosmetics/personal care, etc...

In fertilizers, KOH usually interacts with other ingredients in acid-base reactions and thus practically no free KOH is left in the final product. In some cases, up to 20% of free KOH can still be present in the fertilizer. In that case, the fertilizer also has an intended pH-correction function.

KOH is used during the production phase of various cleaning products although in most case the amounts in the end products are limited. The KOH will be diluted and will interact with other ingredients in acid-base reactions and thus practically no free KOH is left in the final product. Product categorization for professional cleaning products with remaining free KOH after formulation can be found in the table below.

**Table 2: Product categorization for professional cleaning products with remaining free KOH after formulation**

Product type	'free KOH' content	pH range	Remarks concerning RMM/OC
Floor strippers	<10%	>13	
Oven cleaners	5-20%	>13	
Floor degreasers	<5%	>12.5	
Drain openers	<30%	>13	
Dish washing products	5-30%	>13	(concentrated product)
interior heavy duty cleaners	<5%	>12.5	

### Professional oven cleaners

Oven cleaners are strong degreasers and they are suitable for cleaning ovens, grills, etc. Oven cleaners contain strong alkaline ingredients. Strong alkali is effective in removing burned-on contamination. There are trigger sprays and spray cans. When using a spray can, foam is formed on the target area. After spraying, the oven door is closed and the foam has to soak 30 minutes. Then the oven is wiped clean with a wet cloth or sponge and one has to rinse frequently. The maximum content of potassium hydroxide in a spray can is 10%. The product is either a gel, which leads to large droplets upon spraying (100% >10 µm), or a liquid which is applied as a foam with a special trigger also leading to less aerosol.

The frequency of application is 1 event per day and the duration is 10 minutes per event. Spraying should be done into cold oven. There is potential exposure to hands and arms. One can spray up to 1g product per second, by hand-held ready-to-use trigger spray or foam sprayer.

### Professional floor strippers

Floor strippers in I&I applications are not used. The highly alkaline products are dosed 15-20% and per 10 m<sup>2</sup> 1-2 L stripper solution is applied to the floor with a single disc machine. Usually 10-15 min acting time are necessary between applying and scrubbing the floor. Afterwards the stripper/polish mixture is removed by a vacuum cleaner.

### Drain cleaners

Drain openers open slow running and obstructed drains by dissolving and by loosening grease and organic waste. Liquid drain openers have a maximum KOH content of 30%. The use of liquid drain openers is comparable with the dosing of liquid cleaners. The drain opener must be dosed slowly down the drain. Pellets, which can also be used for opening the drain, have contents up to 90%. The drain opener must be dosed slowly down the drain. One has to wait at least 15 minutes so that the drain opener can clear the blockage.

## 1.1.1.3. Risk management measures

### 1.1.1.3.1. Risk management measures related to workers

The risk management measures related to workers can be found in Table 3. This table applies to both liquid and solid KOH containing products at concentration >2%. Because potassium hydroxide is corrosive, the risk management measures for human health aim to avoid direct contact with the substance. For this reason automated and closed systems should preferably be used for industrial and professional uses of potassium hydroxide. Respiratory protection is needed when aerosols of potassium hydroxide can be formed. Due to the corrosive properties appropriate skin and eye protection is required.

**Table 3: Risk management measures related to worker**

Information type	Data field	Explanation
Containment plus good work practice required	<p><u>Good practice</u>: replacing, where appropriate, manual processes by automated and/or closed processes. This would avoid irritating mists, sprays and subsequent potential splashes:</p> <ul style="list-style-type: none"> <li>• Use closed systems or cover open containers (e.g. screens) (<u>good practice</u>)</li> <li>• Transport through pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) (<u>good practice</u>)</li> <li>• Use of pliers, grip arms with long handles with manual use “to avoid direct contact and exposure by splashes (no working over one’s head)” (<u>good practice</u>)</li> </ul>	Partly based on the EU RRS (2008) for NaOH
Local exhaust ventilation required plus good work practise	Local exhaust ventilation is not required but good practice.	To improve air quality and avoid potential respiratory track irritation in working areas.
General ventilation	General ventilation is <u>good practice</u> unless local exhaust ventilation is present	To improve air quality and avoid potential respiratory track irritation in working areas.
Personal protection equipment (PPE) required under regular working conditions	<ul style="list-style-type: none"> <li>• Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2) (<u>required</u>)</li> <li>• Hand protection: impervious chemical resistant protective gloves (<u>required</u>)               <ul style="list-style-type: none"> <li>○ material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: &gt; 480 min</li> <li>○ material: nitrile-rubber, fluorinated rubber, material thickness: 0.35-0.4 mm, breakthrough time: &gt; 480 min</li> </ul> </li> <li>• Eye protection: chemical resistant goggles must be worn. If splashes are likely to occur, wear tightly fitting safety goggles, face –shield (<u>required</u>)</li> <li>• Wear suitable protective clothing, aprons, shield, protective helmet and suits, if splashes are likely to occur, wear: rubber or plastic boots(<u>required</u>)</li> </ul>	To avoid direct contact with the substance
Other risk management measures related to workers. For example: Particular training systems, monitoring/reporting or auditing systems,	<p>Next measures are <u>required</u>:</p> <ul style="list-style-type: none"> <li>• workers in the risky process/areas identified should be trained a) to avoid to work without respiratory protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of potassium hydroxide and c) to follow the safer procedures instructed by the employer (EU RRS, 2008).</li> </ul>	Partly based on the EU RRS (2008) for NaOH

Information type	Data field	Explanation
specific control guidance.	<ul style="list-style-type: none"> <li>the employer should ascertain that the required PPE is available and used according to instructions</li> </ul>	
Measures related to the design of product (other than concentration) related to workers	<ul style="list-style-type: none"> <li>High viscosity adjustment with aids (good practice)</li> <li>Delivery only as barrel commodity and/or in tank car (good practice)</li> </ul>	to avoid splashes

### 1.1.1.3.2. Risk management measures related to professionals

Because potassium hydroxide is corrosive, the risk management measures for human health should focus on the prevention of direct contact with the substance. For this reason automated and closed systems should preferably be used for professional uses of potassium hydroxide. When automated, closed systems and local exhaust ventilation is less feasible to implement, product related design measures preventing direct eye/skin contact with KOH and preventing formation of aerosols and splashes are more important in addition to the personal protective equipment measures.

Product related design measures are required. These include specific dispensers and pumps etc specifically designed to prevent splashes/spills/exposure to occur.

Table 4 gives an overview of the personal protective equipment recommendations. Based on the KOH concentration in the preparation, a different degree of restriction is proposed.

**Table 4: Personal protective equipment related to professional use**

	KOH concentration in product > 2%	KOH concentration in product between 0.5% and 2%	KOH concentration in product < 0.5%
Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2)	compulsory	good practice	Not needed
Hand protection: In case of potential dermal contact: use impervious chemical resistant protective gloves	compulsory	good practice	Not needed
Protective clothing: If splashes are likely to occur, wear suitable protective clothing, aprons, shield and suits, rubber or plastic boots	compulsory	good practice	Not needed
Eye protection: If splashes are likely to occur, wear tightly fitting chemical resistant safety goggles, face –shield	compulsory	good practice	Not needed

### 1.1.1.3.3. Risk management measures related to environment

Risk management measures related to the environment aim to avoid discharging KOH solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant and undesired pH changes. Adequate control of the pH value during introduction into open waters is required. In general, discharges should be carried out such that pH changes in receiving surface waters are minimised. Most aquatic organisms can tolerate pH values in the range of 6-9, this is also reflected in the description of standard OECD tests with aquatic organisms.

There are additionally some specific environmental risk management measures related to fertilizers containing up to 20% of KOH in the end product. Direct releases to adjacent surface waters should be avoided. Drift should be minimized. And in line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of the fertiliser and the application rate should be adjusted according to the results of the analysis.

#### 1.1.1.4. Waste related measures

Liquid KOH waste should be reused or discharged to industrial wastewater and further neutralized if needed (cfr. RMM related to environment).

### 1.1.2. Exposure estimation

#### 1.1.2.1. Workers exposure

KOH is a corrosive substance at concentrations >2%. For the handling of corrosive substances and formulations, immediate dermal contacts occur only occasionally and it is assumed that repeated daily dermal exposure is negligible. Therefore according to the NaOH EU RAR (2007), dermal exposure to >2% KOH will not be quantitatively assessed. Repeated dermal exposure is negligible for <2% formulations.

KOH is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic effects of KOH after dermal or inhalation exposure are not expected to occur.

#### Measured exposure concentrations

One measured exposure concentration of KOH was available from the textile industry. Even though the use of closed systems for KOH is wide-spread in the majority of the textile industry, an open use measurement for KOH (during cleaning of the machinery) showed less than 0.06 mg/m<sup>3</sup>.

The amount of alkali dust was measured in three sampling locations of a downstream user. The three sampling locations are packaging (filter placed where belt from container and elevator belt meet), personal sampler by operator and placed close to the filling operations. These are the most critical steps for occupational exposure to KOH. The exposure time was respectively 260, 270 and 263 minutes. The inhalable dust fraction was respectively 0.8, 1 and 0.3 mg/m<sup>3</sup>. These measurements are an overestimation because all dust is assumed to originate from alkali. These measurements are therefore not suitable for risk characterization of KOH.

#### Estimated exposure concentrations

The estimated inhalation exposure concentrations to workers are summarized in Table 5. The ECETOC TRA was used to estimate the concentrations. It was assumed that there is no local exhaust ventilation and no respiratory protection unless specified otherwise. The duration of exposure was set at more than 4 hours per day as a worst-case assumption. Professional use was specified where relevant as a worst-case assumption. For the solid, the low dustiness class was selected because KOH is very hygroscopic. Only the most relevant PROCs were considered in the assessment.

There is no need to quantitatively derive dermal exposure estimations because a DNEL for dermal exposure is not applicable.

**Table 5: Long-term inhalation exposure concentrations to workers (estimated exposure concentrations)**

PROC	PROC description	Liquid (mg/m <sup>3</sup> )	Solid (mg/m <sup>3</sup> )
PROC 1	Use in closed process, no likelihood of exposure	0.23	0.01
PROC 2	Use in closed, continuous process with occasional controlled exposure (e.g. sampling)	0.23	0.01
PROC 3	Use in closed batch process (synthesis or formulation)	0.23	0.1
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	0.23	0.2 (with LEV)
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or	0.23	0.2 (with LEV)

PROC	PROC description	Liquid (mg/m <sup>3</sup> )	Solid (mg/m <sup>3</sup> )
	significant contact)		
<b>PROC 7</b>	Spraying in industrial settings and applications	0.23	Not applicable
<b>PROC 8a/b</b>	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated or dedicated facilities	0.23	0.5
<b>PROC 9</b>	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	0.23	0.5
<b>PROC10</b>	Roller application or brushing of adhesive and other coating	0.23	0.5
<b>PROC11</b>	Spraying outside industrial settings or applications	0.23	0.2 (with LEV)
<b>PROC13</b>	Treatment of articles by dipping and pouring	0.23	0.5
<b>PROC14</b>	Production of preparations or articles by tableting, compression, extrusion, pelettisation	0.23	0.2 (with LEV)
<b>PROC15</b>	Use a laboratory reagent	0.23	0.1
<b>PROC19</b>	Hand-mixing with intimate contact and only PPE available.	0.23	0.5
<b>PROC23</b>	Open processing and transfer operations (with minerals) at elevated temperature	0.23	0.4 (with LEV and RPE(90%))
<b>PROC24</b>	High (mechanical) energy work-up of substances bound in materials and/or articles	0.23	0.5 (with LEV and RPE(90%))

PROC 26 was considered to mainly applicable to metals industry. Handling of inorganic substances is assumed to be included in the existing PROCs assessed.

### Summary of the exposure values

The summary of exposure concentrations to workers, taken forward to risk characterization, is given in Table 6.

**Table 6: Summary of exposure concentration to workers**

Routes of exposure	Concentrations	Justification
<b>Dermal exposure (in mg/cm<sup>2</sup>)</b>	Qualitative	KOH products with a concentration > 2% are corrosive, therefore effective control measures are expected to be in place to prevent dermal exposure. Furthermore protective clothing and gloves are considered to be used consistently when handling corrosive substances. Repeated daily dermal exposure to the pure substance is therefore considered negligible.  Dilutions of NaOH containing less than 2% of the substance do not have corrosive properties. For this concentration a qualitative risk characterization is proposed.
<b>Inhalation exposure (in mg/m<sup>3</sup>)</b>	0.5	The estimated inhalation concentrations are larger than the measured value available. These will be used for risk characterisation. The maximum estimated inhalation concentration is 0.23 mg/m <sup>3</sup> for liquid and 0.5 mg/m <sup>3</sup> for solid.

### 1.1.2.2. Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore *indirect* exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

### 1.1.2.3. Environmental exposure

Analogously as argued in the EU RAR on NaOH (2007), the risk assessment for the environment will focus solely on the aquatic environment, when applicable including STPs/WWTPs, as the emissions of KOH in the different life-cycle stages (production and use) mainly apply to (waste) water. The aquatic effect and risk assessment will only deal with the effect on organisms/ecosystems due to possible pH changes related to OH<sup>-</sup> discharges, as the toxicity of the K<sup>+</sup> ion is expected to be insignificant compared to the (potential) pH effect. Only the local scale will be addressed, including sewage treatment plants (STPs) or waste water treatment plants (WWTPs) when applicable, both for production and industrial use. Any effects that might occur would be expected to take place on a local scale and therefore it was decided as not meaningful to include the regional or continental scale in this risk assessment. Furthermore, the high water solubility and very low vapour pressure indicate that KOH will be found predominantly in water. Significant emissions to air are not expected due to the very low vapour pressure of KOH. Significant emissions to the terrestrial environment are not expected either. The sludge application route is not relevant for the emission to agricultural soil, as no sorption of KOH to particulate matter will occur in STPs/WWTPs.

The exposure assessment for the aquatic environment will only deal with the possible pH changes in STP effluent and surface water related to the OH<sup>-</sup> discharges at the local scale.

#### 1.1.2.3.1. Environmental releases

It is envisaged that the pH of discharges would also be strictly controlled by the industry involved, often in response to local requirements. Usually, the pH of waste water discharges is controlled and normally proper regulations are in place. Therefore a significant increase of the pH of the receiving water is not expected. Generally the change in pH of the receiving water should stay within a tolerated range of the pH at the effluent site, and for this reason adverse effects on the aquatic environment are not expected due to production or use of KOH, if emissions of waste water are controlled by appropriate pH limits and/or dilutions in relation to the natural pH and buffering capacity of the receiving water (OECD SIAR, 2002).

#### 1.1.2.3.2. Exposure concentration in waste water treatment plants (WWTP)

Referring to the RMMs related to the environment, aiming to avoid discharging KOH solutions into municipal wastewater unless, the influent of municipal waste water treatment plants are normally circum-neutral and strongly buffered and therefore no effect on the biological activity is expected.

#### 1.1.2.3.3. Exposure concentration in aquatic pelagic compartment

If emitted to surface water, sorption to particulate matter and sediment will be negligible. An addition of KOH to surface water may increase the pH, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO<sub>2</sub>), the bicarbonate ion (HCO<sub>3</sub><sup>-</sup>) and the carbonate ion (CO<sub>3</sub><sup>2-</sup>):



If the pH is < 6, un-ionised CO<sub>2</sub> is the predominant species and the first equilibrium reaction is most important for the buffer capacity. At pH values of 6-10 the bicarbonate ion (HCO<sub>3</sub><sup>-</sup>) is the predominant species and at pH values > 10 the carbonate ion (CO<sub>3</sub><sup>2-</sup>) is the predominant species. In the majority of natural waters the pH values are between 6 and 10, thus the bicarbonate concentration and the second equilibrium reaction are most important for the buffer capacity (Rand, 1995; De Groot and Van Dijk, 2002; OECD, 2002). UNEP (1995) reported the bicarbonate concentration for a total number of 77 rivers in North-America, South-America, Asia, Africa, Europe and Oceania. The 10th-percentile, mean and 90th-percentile concentrations were 20, 106 and 195 mg/l, respectively (OECD, 2002). To underline the importance of the buffer capacity, Table 7 is included with the concentration of KOH needed to increase the pH to a value of 9.0 at different bicarbonate concentrations. It should be realised that the final pH could be slightly lower than 9.0 because at initial pH values below 8 there is some CO<sub>2</sub> available to buffer the pH (OECD SIAR potassium hydroxide, 2002).

The alkalinity, defined as the acid-neutralising (i.e. proton accepting) capacity of the water, thus the quality and quantity of constituents in water that result in a shift in the pH toward the alkaline site of neutrality, is

determined for > 99% by the concentrations of bicarbonate ( $\text{HCO}_3^-$ ), carbonate ( $\text{CO}_3^{2-}$ ) and hydroxide ( $\text{OH}^-$ ) (Rand, 1995), with bicarbonate being the predominant species at pH values in the range of 6-10 (see also above). Hydroxide is only relevant in alkaline waters. Thus, the data in Table 7 are useful to estimate pH increases in natural waters (most of them having a pH value of 7-8), if data on KOH additions and bicarbonate concentrations are available. The alkalinity is determined from acid/base titration or can be calculated from the calcium concentration, as follows (De Schampelaere et al., 2003; Heijerick et al., 2003):

$$\text{Log (alkalinity in eq/l)} = - 0.2877 + 0.8038 \text{ Log (Ca in eq/l)}$$

**Table 7: Concentration of KOH needed to increase pH to a value of 9 (OECD SIAR potassium hydroxide, 2002)**

Buffer capacity	Concentration KOH (mg/l)	Concentration K (mg/l)	Concentration KOH (mM)
0 mg/l $\text{HCO}_3^-$ (distilled water)	0.56	0.39	0.010
20 mg/l $\text{HCO}_3^-$ (10 <sup>th</sup> percentile 77 rivers)	0.86	0.60	0.015
106 mg/l $\text{HCO}_3^-$ (mean value of 77 rivers)	4.51	3.14	0.080
195 mg/l $\text{HCO}_3^-$ (90 <sup>th</sup> percentile 77 rivers)	8.30	5.78	0.148

Based on the neutralized environmental releases and the fate in the aquatic compartment described above, there is no environmental impact on the receiving surface water.

#### 1.1.2.3.4. Exposure concentration in sediments

The sediment compartment is not included in this CSA, because it is not considered relevant for KOH. If emitted to the aquatic compartment, sorption to sediment particles will be negligible.

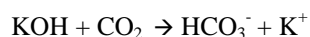
#### 1.1.2.3.5. Exposure concentrations in soil and groundwater

The terrestrial compartment is not included in this CSA, because it is not considered relevant for KOH. With respect to the fate of KOH in soil the following information is available. If emitted to soil, sorption to soil particles will be negligible. Depending on the buffer capacity of the soil,  $\text{OH}^-$  will be neutralised in the soil pore water or the pH may increase.

An additional consideration should be made related to the use of fertilizers containing up to 20% of KOH in the end product. In that case, the fertilizer has an intended pH-correction impact on the soil and following the risk management measures on good agricultural practice, agricultural soil should be analysed prior to application of the fertiliser and the application rate should be adjusted according to the results of the analysis. This way, the impact to terrestrial organisms should be beneficial rather than adverse.

#### 1.1.2.3.6. Atmospheric compartment

The air compartment is not included in this CSA because it is considered not relevant for KOH. With respect to the fate of NaOH in air the following information is available from EU RAR (2007). If emitted to air as an aerosol in water, NaOH will be rapidly neutralised as a result of its reaction with  $\text{CO}_2$  (or other acids) and the same will apply to KOH as stated in the KOH SIAR. The salts will be washed out by rain:



#### 1.1.2.3.7. Exposure concentration relevant for the food chain (Secondary poisoning)

Bioaccumulation in organisms is not relevant for KOH. Therefore, there is no need to perform a risk assessment for secondary poisoning.



## 1.2. Exposure Scenario 2 : Consumer use of solid and liquid KOH (excl. batteries)

### 1.2.1. Exposure scenario

#### 1.2.1.1. Short title of the exposure scenario

SU21: private households

PROC not applicable for this ES

PC 9 Coatings and Paints, Fillers, Putties, Thinners  
PC12 Fertilizers  
PC20 Products such as pH-regulators, flocculants, precipitants, neutralization agents, other  
PC28 Perfumes, fragrances  
PC35 Washing and Cleaning Products (including solvent based products)  
PC39 Cosmetics

However, it could potentially also be used in other chemical product categories (PC 0 – 40).

AC not applicable for this ES

#### 1.2.1.2. Description of activities, processes and operational conditions covered in the exposure scenario

Less than 5% of the KOH production is applied in wide dispersive uses and enters in consumer products paint and varnish removers, drain cleaners (Howell, 1991; Leape et al., 1971), degreasing agents (Swanson et al., 1995) and dairy pipeline cleaners (Edmonson, 1987).

The amounts used will interact with other ingredients in acid-base reactions and thus practically no KOH is left in the final consumer product. However, some cleaning products may contain 0.25-0.45% of KOH in the final formulation. Some toilet cleaners may contain up to 1.1% and certain soaps contain up to 0.5% of KOH in the final formulation.

#### 1.2.1.3. Risk management measures

##### 1.2.1.3.1. Risk management measures related to consumers

The risk management measures related to consumers are mainly related to prevent accidents.

##### Measured related to the design of the product

- It is required to use resistant labelling-package to avoid its auto-damage and loss of the label integrity, under normal use and storage of the product. The lack of quality of the package provokes the physical loss of information on hazards and use instructions.
- It is required that household chemicals, containing potassium hydroxide for more than 2%, which may be accessible to children should be provided with a child-resistant fastening (currently applied) and a tactile warning of danger (Adaptation to Technical Progress of the Directive 1999/45/EC, annex IV, Part A and Article 15(2) of Directive 67/548 in the case of, respectively, dangerous preparations and substances intended for domestic use). This would prevent accidents by children and other sensitive groups of society.
- It is required that appropriate use instructions, and product information should always be provided to consumers. This clearly can reduce the risk of misuse. For reducing the number of accidents, it is advisable to use these products in the absence of children or other sensitive groups. To prevent improper use of potassium hydroxide, instructions for use should contain a warning against dangerous mixtures

- It is advisable to deliver only in very viscous preparations
- It is advisable to deliver only in small amounts

#### Instructions addressed to consumers

- Keep out of reach of children.
- Do not apply product into ventilator openings or slots.

#### PPE required under regular conditions of consumer use

	KOH concentration in product > 2%	KOH concentration in product between 0.5% and 2%	KOH concentration in product < 0.5%
Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2)	required	good practice	Not needed
Hand protection: In case of potential dermal contact: use impervious chemical resistant protective gloves	required	good practice	Not needed
Eye protection: If splashes are likely to occur, wear tightly fitting goggles, face –shield	required	good practice	Not needed

#### 1.2.1.3.2. Risk management measures related to environment

There are no specific risk management measures related to environment.

#### 1.2.1.4. Waste related measures

Wasted material and its containers must be disposed of in a safe way (e.g. by returning to a public recycling facility). If container is empty, trash as regular municipal waste.

## 1.2.2. Exposure estimation

### 1.2.2.1. Consumer exposure

For consumer exposure it is important to stress that potassium hydroxide exposure is an external exposure. Contact with tissue and water will give potassium and hydroxide ions which are abundantly present in the body.

If the recommended RMMs are respected, local exposure through inhalation will not be higher compared to inhalation exposures in ES3 (Section 1.3.2.1). Therefore, the consumer exposure through inhalation is not further quantitatively assessed.

Potassium hydroxide is a food additive, listed as E525 in Annex 1 of Directive 95/2/EU. This means that KOH is a general food additive to be used following the “quantum satis” principle: as much as necessary according to GMP (European Union, 1995).

The concentration of potassium is limited under the EU Directive on Drinking Water Quality 80/778/EEC. The potassium guide level is 10 mg/l and the maximum allowable concentration is 12 mg/l (European Economic Community, 1980). The taste threshold of KOH in water is reported to be 1 to 50 mg/l (Mc Kee et al., 1963).

The normal daily dietary intake of potassium in humans is approximately 2 - 4 g (FASEB, 1979), typically 2 – 6 g in the US diet (Saxena, 1989). The daily dietary intake of K is recommended to be approximately 2.4 g or

more because this is associated with a reduced risk of stroke-related mortality (Burgess et al., 1999). In line with the conclusion for NaOH (EU RAR, 2007), it was concluded that the potassium uptake due to the use of KOH containing products is negligible compared to the daily dietary intake of potassium ions. The effect of potassium intake is not further considered in this dossier.

Since accidental exposure is normally excluded from an EU chemical safety assessment and accidental exposure is considered in the OECD SIAR of KOH (2002, Section 2.2, page 5), accidental exposure will not be further assessed in this dossier.

### **1.2.2.2. Indirect exposure of humans via the environment (oral)**

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore *indirect* exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

### **1.2.2.3. Environmental exposure**

Consumer uses relate to already diluted products which will be quickly further neutralized in the sewer and therefore will not reach a WWTP or surface water.

## 1.3. Exposure Scenario 3 : Consumer use, service life and waste stage of KOH in batteries

### 1.3.1. Exposure scenario

#### 1.3.1.1. Short title of the exposure scenario

SU21: private households

PROC not applicable for this ES

PC not applicable for this ES

AC 3: Electrical batteries and accumulators

#### 1.3.1.2. Description of activities, processes and operational conditions covered in the exposure scenario

Aqueous potassium hydroxide is employed as electrolyte in alkaline batteries based on nickel-cadmium and manganese dioxide-zinc. Potassium hydroxide is preferred over sodium hydroxide because its solutions are more conductive. KOH is still present in alkaline batteries, but the substance is strictly confined in the battery containers and is not in direct contact with consumers.

The industrial and professional uses of KOH in batteries (incl. recycling operations) are covered under ES 1. This ES focuses on the consumer use, the service life and the end-of-life stage of KOH in batteries. Batteries are sealed articles and during normal use its contents, including KOH, will not be directly released and emission from KOH in these life-cycle stages should be minimal.

#### 1.3.1.3. Risk management measures

##### 1.3.1.3.1. Risk management measures related to consumers

Measures related to the design of the product: It is required to use completely sealed articles with a long service life maintenance.

##### 1.3.1.3.2. Risk management measures related to environment

Due to the negligible exposure of KOH during normal battery use and disposal, there are no specific risk management measures related to environment.

##### 1.3.1.4. Waste related measures

Batteries should be recycled as much as possible (e.g. by returning to a public recycling facility). Recovery of KOH from alkaline batteries includes removing the electrolyte, collection and neutralization with sulphuric acid and carbon dioxide. The occupational exposure related to these steps are considered in the exposure scenario on industrial and professional use of KOH.

### 1.3.2. Exposure estimation

#### 1.3.2.1. Consumer exposure

Consumer exposure is negligible because batteries are sealed articles with a long service life maintenance.

### 1.3.2.2. Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore *indirect* exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

### 1.3.2.3. Environmental exposure

The environmental release from the consumer use during service life is negligible because batteries are sealed articles with a long service life. After use, batteries normally are recycled and even in case it is disposed as municipal waste, KOH is not expected to cause a significant (pH) effect to the environment when incinerated or landfilled.

## 1.4. Regional exposure concentrations

Any effects of KOH that might occur would be expected to take place on a local scale and therefore it was decided as not meaningful to include the regional or continental scale in this risk assessment (cfr. EU RAR for NaOH, 2007). Predicted environmental concentrations (PECs) of KOH cannot be calculated, only a summary of measured levels is provided.

The emissions of KOH during production and use mainly apply to the aquatic environment. In water (including pore water of sediment and soil), KOH dissociates into the potassium ion ( $K^+$ ) and hydroxyl ion ( $OH^-$ ), both are ubiquitous in nature.

### 1.4.1. Freshwater (surface waters)

The concentration of hydroxyl ions ( $OH^-$ ) in the environment has been determined very extensively via pH measurements. Geochemical, hydrological and/or biological processes mainly determine the pH of an aquatic ecosystem. The pH is an important parameter of aquatic ecosystems and it is a standard parameter of water quality monitoring programs. The most important freshwater aquatic ecosystems of the world revealed average annual pH values between 6.5 and 8.3 but lower and higher values have been measured in other aquatic ecosystems. In aquatic ecosystems with dissolved organic acids a pH of less than 4.0 has been measured, while in waters with a high chlorophyll content the bicarbonate assimilation can result in pH values of higher than 9.0 at midday (OECD, 2002, from UNEP 1995).

Also potassium has been measured extensively in aquatic ecosystems. For example, UNEP (1995) reported the concentration for a total number of 75 rivers in North America, South-America, Asia, Africa, Europe and Oceania. The 10<sup>th</sup> -percentile, mean and 90<sup>th</sup> -percentile were 0.8 , 3.2 and 6.0 mg/l, respectively. The potassium concentration of topsoils is 0.2-3.3%, and that of seawater is 380 mg/l (Tait, 1980).

For European freshwaters, there are extensive databases on physico-chemical properties, including pH, hardness (calculated from the measured calcium and magnesium concentration), alkalinity (determined by acid/base titration or calculated from the calcium concentration, see further Section 3.1.3.2 – CSR KOH PPC SAS) and potassium concentration. In the framework of the EU Risk Assessment Report on Zn Metal (The Netherlands, 2004), data on physico-chemical properties of freshwaters in individual European countries and the combined data for freshwaters in European countries were collected and reported by De Schampelaere et al. (2003) and Heijerick et al. (2003). The combined European data for the above physico-chemical properties, all relevant for pH changes, are summarised in Table 8. The data in this table are based on 1991-1996 data for 411 European locations, extracted from the 'GEMS/Water database' (Global Environmental Monitoring System) that is mainly aimed on the large river systems. A correlation analysis on the data from all 411 locations indicate that all parameters listed in Table 8 are positively correlated, i.e. an increased pH is associated with increased concentrations of Ca, Mg and Na and increased hardness and alkalinity (De Schampelaere et al., 2003; Heijerick et al., 2003).

The variation in the above physico-chemical properties of the large river systems in different European countries is rather small, with exception of some areas in the Nordic countries (Denmark, Sweden, Norway and Finland) which are characterised by 'soft water' conditions, i.e. a hardness <24 mg  $CaCO_3/l$  and low pH. For example, in Sweden the 50<sup>th</sup> percentile value for hardness is 15 mg  $CaCO_3/l$ , which is 10-times lower than that for whole Europe. In Sweden the 50<sup>th</sup> percentile value for pH is just below 7, which is about 1 pH unit lower than that for whole Europe (De Schampelaere et al., 2003; Heijerick et al., 2003; The Netherlands, 2004).

**Table 8: Distribution of European freshwaters (De Schampelaere et al., 2003; Heijerick et al., 2003)**

Percentile value	pH	Hardness <sup>1</sup> (mg/l, as CaCO <sub>3</sub> )	Alkalinity (mg/l, as CaCO <sub>3</sub> )
5 <sup>th</sup> percentile	6.9	26	3
10 <sup>th</sup> percentile	7.0	41	6
20 <sup>th</sup> percentile	7.2	70	15
30 <sup>th</sup> percentile	7.5	97	31
40 <sup>th</sup> percentile	7.7	126	53
50 <sup>th</sup> percentile	7.8	153	82
60 <sup>th</sup> percentile	7.9	184	119
70 <sup>th</sup> percentile	7.9	216	165
80 <sup>th</sup> percentile	8.0	257	225
90 <sup>th</sup> percentile	8.1	308	306
95 <sup>th</sup> percentile	8.2	353	362

1) Hardness: total hardness, calculated from the Ca and Mg concentration

### 1.3.2. Seawater

In over 97% of the seawater in the world, the salinity (the amount of dissolved inorganic constituents), is 35‰ (promille, in g/kg). The major constituents of seawater at 35 ‰ are Cl<sup>-</sup> (19.35 g/kg), Na<sup>+</sup> (10.77 g/kg), SO<sub>4</sub><sup>2-</sup> (2.71 g/kg), Mg<sup>2+</sup> (1.29 g/kg), Ca<sup>2+</sup> (0.41 g/kg), K<sup>+</sup> (0.40 g/kg) and HCO<sub>3</sub><sup>-</sup> (0.142 g/kg, being the carbonate alkalinity expressed as though it were all HCO<sub>3</sub><sup>-</sup>, as this is the dominant species in seawater; the concentrations of CO<sub>2</sub> and CO<sub>3</sub><sup>2-</sup> in seawater are very low compared to that of HCO<sub>3</sub><sup>-</sup>) (Stumm and Morgan, 1981).

The pH of seawater (ocean water) is normally 8.0-8.3, which is very similar to the vast majority of European freshwaters (8.0-8.2, Table 8). The bicarbonate (HCO<sub>3</sub><sup>-</sup>) concentration in seawater (142 mg/kg, equivalent to 137 mg/l) is between the mean HCO<sub>3</sub><sup>-</sup> concentration (106 mg/l) and the 90th percentile HCO<sub>3</sub><sup>-</sup> concentration (195 mg/l) in European freshwaters, indicating a relatively high buffer capacity in seawater.

The observed pH values in European freshwater and seawater are within the tolerable ranges of the aquatic ecosystems.

## 2. RISK CHARACTERISATION

The potential for human health effects is the occurrence of local effects after acute and repeated exposure at those places where KOH is produced and/or used. This is because KOH is not expected to become systemically available in the body under normal handling and use conditions, i.e. neither the concentration of potassium in the blood nor the pH of the blood will be significantly affected.

Workers are protected from dermal exposure to avoid direct dermal contacts. Techniques and equipment (including PPE) are used providing a high level of protection from direct dermal contact. Dermal exposure to corrosive concentrations during normal handling and use of corrosive substances and formulations is therefore considered negligible and is not quantitatively assessed. Eye protection is obligatory for activities where direct handling of KOH may occur. However, dermal exposure to non-corrosive dilutions of KOH (concentrations < 2%) may occur. Dermal exposure to such non-corrosive dilutions of KOH is taken into account.



## 2.1. Exposure Scenario 1: Industrial and professional use of KOH

### 2.1.1. Human health

#### 2.1.1.1. Workers

**Table 9: Risk characterisation for workers**

Route		ES 3- exposure concentrations (EC)	Leading toxic end point / Critical effect	DNEL	Risk characterisation ratio
Dermal-local	Acute	Not relevant	Skin/eye irritation/corrosion	1 mg/m <sup>3</sup>	0.5
	Long term	Not relevant	Skin/eye irritation/corrosion		
Inhalation-local	Acute / Long term	0.5 mg/m <sup>3</sup>	Respiratory tract irritation	1 mg/m <sup>3</sup>	0.5

Since the risk characterisation ratios are below one, it is demonstrated that industrial and professional use of KOH is adequately under control for workers and professionals.

#### 2.1.1.2. Indirect exposure of humans via the environment

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore indirect exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

### 2.1.2. Environment

#### 2.1.2.1. Aquatic compartment (including sediment and secondary poisoning)

Taking into account the recommended risk management measures for environment and the existing EU

Directives for pH control for surface water and the data of many Member States on (additional) national regulations to control the pH of waste waters (STP influents) and surface waters it is concluded that STPs and surface waters are sufficiently protected with regard to pH changes (cfr. EU RAR for NaOH, 2007, section 3.3.1.1).

It is noted that it cannot be excluded that there are (some) sites with KOH discharges to the aquatic environment, resulting in significant pH changes and effects on biological STPs/WWTPs or receiving surface waters. However, the available data clearly indicate that neutralisation of KOH containing waste waters and effluents is common practice, either from a legal point of view (legislation for surface waters) or from a practical point of view (protection of the functioning of biological STPs/WWTPs) (EU RAR, 2007, Section 3.3.1.2).

Therefore, the industrial and professional use of KOH is adequately under control for environment.

## 2.2. Exposure Scenario 2 : Consumer use of KOH

### 2.2.1. Human health

#### 2.2.1.1. Consumers

As potassium hydroxide is not expected to become systemically available in the body under normal handling and use conditions, the risk characterisation for consumers will focus on possible risks from acute exposure (local effects).

**Table 10 Risk characterisation for consumers**

Route		ES 4- exposure concentrations (EC)	Leading toxic end point / Critical effect	DNEL	Risk characterisation ratio
Dermal-local	Acute	Not relevant	Skin/eye irritation/corrosion		<p><b>Qualitative (case KOH concentrations <math>\geq</math> 2%):</b> Consumers can be exposed to corrosive concentrations. However, dermal exposure to KOH is considered to occur only accidentally if the required protection is strictly adhered to. Therefore, a conclusion on adequately controlled risks is justifiable for scenarios in which corrosive and irritating concentrations of KOH are handled.</p> <p><b>Qualitative (case KOH concentrations <math>&lt;</math> 2% and <math>&gt;</math> 0.5%):</b> When existing controls and recommended RMMs are applied, safe use can be concluded.</p> <p><b>Qualitative (case KOH concentrations <math>&lt;</math> 0.5%):</b> Safe use can be concluded because no health effects are observed.</p>
	Long term	Not relevant	Skin/eye irritation/corrosion		
Inhalation-local	Acute	Not relevant	Respiratory tract irritation		<p><b>Qualitative:</b> KOH will be rapidly neutralised as a result of its reaction with CO<sub>2</sub> (or other acids). Since the KOH concentration and amount handled are smaller compared to professional use and since the DNEL and RMMs are similar, safe use can be concluded for consumer use.</p>
	Long term	Not relevant	Respiratory tract irritation		

Following the normal use of corrosive and irritating concentrations of potassium hydroxide it is concluded that the substance is of no risk for consumers if the required protection is used.

#### 2.2.1.2. Indirect exposure of humans via the environment

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore *indirect* exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

## 2.2.2. Environment

Consumer uses relate to already diluted products which will quickly be further neutralized in the sewer, well before reaching a WWTP or surface water. Therefore consumer use of KOH is adequately controlled for the environment.

## 2.3. Exposure Scenario 3 : Consumer use, service life and waste stage of KOH in batteries

### 2.3.1. Human health

#### 2.3.1.1. Consumers

Consumer exposure is zero because batteries are sealed articles with a long service life maintenance. Therefore, consumer use of KOH in batteries is adequately under control.

#### 2.3.1.2. Indirect exposure of humans via the environment

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for KOH. Any potential for exposure to KOH due to environmental releases will only have relevance at the local scale. Any pH effect of local releases will be neutralised by the buffer capacity of the receiving water and therefore no pH impacts at the regional scale related to KOH releases should be expected. Therefore *indirect* exposure of humans via the environment (oral) is not relevant in the case of KOH. This conclusion is similar to OECD SIAR (2002).

### 2.3.2. Environment

The environmental release from the consumer use and the service life are negligible because batteries are sealed articles with a long service life. After use, batteries should be recycled as much as possible but in case of disposal as municipal waste, KOH is not expected to cause a significant (pH) effect to the environment when incinerated or landfilled. Therefore, the use of KOH in alkaline batteries is adequately under control for the environment.