



# FICHE DE DONNEES DE SECURITE

## Primisil™ 5 1 1

Conformément au règlement (CE) no 453/2010  
Conformément au règlement (CE) no 1907/2006

### SECTION 1: IDENTIFICATION DE LA SUBSTANCE/DU MÉLANGE ET DE LA SOCIÉTÉ/L'ENTREPRISE

#### 1.1. Identificateur de produit

Nom commercial Primisil™ 5 1 1  
Numéro d'enregistrement REACH 01-2119488518-22-0004  
No CAS 68855-54-9  
No CE 272-489-0

#### 1.2. Utilisations identifiées pertinentes de la substance ou du mélange et utilisations déconseillées

Utilisations identifiées Aide à la filtration.  
Utilisations déconseillées Aucun

#### 1.3. Renseignements concernant le fournisseur de la fiche de données de sécurité

Distributeur Imerys Filtration France  
7 rue de stade - BP 42  
FR - 15300 Murat  
France  
Tel. +33 (0) 4 71 20 00 49  
Fax. +33 (0) 4 71 20 32 28  
SDS.expert@imerys.com

#### 1.4. Numéro d'appel d'urgence

CHEMTREC + 1 703 527 3887

### SECTION 2: IDENTIFICATION DES DANGERS

#### 2.1. Classification de la substance ou du mélange

Classification (CE 1272/2008)

Risques Physiques et Chimiques	Non classé.
Pour l'homme	Non classé.
Pour l'environnement	Non classé.

Classification (67/548/CEE) Non classé.

L'intégralité du texte des phrases de risque et des mentions de danger figure à la Section 16.

Pour l'homme

Ce produit ne satisfait pas les critères de classification en tant que substance dangereuse définis dans le Règlement CE 1272/2008 et la Directive 67/548/CEE. Selon le type de manipulation et d'utilisation (p. ex., broyage, séchage), des particules de silice cristalline alvéolaire sont susceptibles d'être générées dans l'air. Une inhalation prolongée et/ou massive de poussières de silice cristalline alvéolaire peut provoquer une fibrose pulmonaire, communément appelée silicose. Les principaux symptômes de la silicose sont la toux et l'essoufflement. L'exposition professionnelle aux poussières de silice cristalline alvéolaire doit être surveillée et contrôlée.

Pour l'environnement

On ne considère pas que ce produit ait des effets néfastes sur l'environnement.

Risques Physiques et Chimiques

Ce produit est une substance inorganique et ne répond pas aux critères de PBT ou de vPvB mentionnés à l'annexe XIII de REACH. Ce produit doit être manipulé avec précaution pour éviter la génération de poussières.

#### 2.2. Éléments d'étiquetage

No CE 272-489-0  
Étiquette Conforme A La Norme (CE) N° 1272/2008  
Aucun pictogramme requis.

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## 2.3. Autres dangers

Non classifié dans la catégorie PBT/vPvB selon les critères actuels de l'UE.

## SECTION 3: COMPOSITION/INFORMATIONS SUR LES COMPOSANTS

### 3.1. Substances

Diatomaceous Earth, Flux Calcined	100%
No CAS : 68855-54-9	No CE : 272-489-0
Classification (CE 1272/2008) Non classé.	Classification (67/548/CEE) Non classé.

L'intégralité du texte des phrases de risque et des mentions de danger figure à la Section 16.

Numéro d'enregistrement REACH 01-2119488518-22-0004

No CAS 68855-54-9

No CE 272-489-0

Commentaires Sur La Composition

Impuretés:

Cristobalite: CAS-No.: 14464-46-1 EC No.: 238-455-4

Ce produit contient moins d'1 % de cristobalite alvéolaire; cristobalite alvéolaire étant classifié comme STOT RE1.

## SECTION 4: PREMIERS SECOURS

### 4.1. Description des premiers secours

Informations générales

Aucun symptôme aigu ni à retardement n'est observé.

Inhalation

Aller à l'air frais et se reposer. Consulter un médecin si les troubles persistent.

Ingestion

Rincer soigneusement la bouche. Consulter un médecin si les troubles persistent. Ne pas faire vomir.

Contact avec la peau

Laver la peau avec de l'eau et du savon. Utiliser une lotion adéquate pour rétablir l'humidité de la peau.

Contact avec les yeux

Ne pas se frotter les yeux. Rincez abondamment à l'eau claire et consultez un médecin si l'irritation persiste.

### 4.2. Principaux symptômes et effets, aigus et différés

Inhalation

Respirer des poussières de silice cristalline pendant de longues périodes peut endommager vos poumons.

La silice cristalline (cristobalite) est une cause connue de silicose, une maladie des poumons progressive, parfois fatale.

### 4.3. Indication des éventuels soins médicaux immédiats et traitements particuliers nécessaires

Pas de recommandations spécifiques de premiers soins notées.

## SECTION 5: MESURES DE LUTTE CONTRE L'INCENDIE

### 5.1. Moyens d'extinction

Moyens d'extinction

Ce produit est incombustible. Aucun moyen d'extinction spécifique n'est nécessaire.

### 5.2. Dangers particuliers résultant de la substance ou du mélange

Risques particuliers

Non combustible. Pas de décomposition thermique dangereuse.

### 5.3. Conseils aux pompiers

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Procédures De Lutte Contre L'Incendie

Aucune protection spécifique anti-incendie n'est requise. Employer un agent extincteur qui convient aux feux environnants.

## SECTION 6: MESURES À PRENDRE EN CAS DE DISPERSION ACCIDENTELLE

### 6.1. Précautions individuelles, équipement de protection et procédures d'urgence

Évitez la génération de poussières en suspension dans l'air, portez des équipements de protection personnelle conformes à la législation nationale. Assurer une ventilation efficace.

### 6.2. Précautions pour la protection de l'environnement

Ne pas rejeter à l'égout, dans l'environnement terrestre ou dans les cours d'eau. Éviter la dispersion de poussières ou de matières contaminées.

### 6.3. Méthodes et matériel de confinement et de nettoyage

Évitez de balayer à sec et utilisez des systèmes de nettoyage avec vaporisation d'eau ou par le vide pour éviter la génération de poussières en suspension dans l'air. Portez des équipements de protection personnelle conformes à la législation nationale en vigueur. Recueillir dans des récipients et bien sceller.

### 6.4. Référence à d'autres sections

Pour obtenir des informations sur la protection individuelle, voir la rubrique 8. Pour obtenir des informations sur l'élimination, voir la rubrique 13.

## SECTION 7: MANIPULATION ET STOCKAGE

### 7.1. Précautions à prendre pour une manipulation sans danger

Évitez la génération de poussières en suspension dans l'air. Prévoyez des systèmes d'aspiration appropriés aux emplacements où les poussières en suspension dans l'air sont générées. En cas de ventilation insuffisante, portez des équipements de protection respiratoire adaptés. Manipulez les produits emballés avec précaution pour éviter tout éclatement accidentel. Si vous avez besoin de conseils sur les techniques de manipulation en toute sécurité, contactez votre fournisseur ou consultez le Guide de bonnes pratiques auquel il est fait référence à la section 16. Ne pas manger, boire et fumer dans les zones de travail; se laver les mains après chaque utilisation; enlever les vêtements contaminés et l'équipement de protection avant d'entrer dans une zone de restauration.

### 7.2. Conditions d'un stockage sûr, y compris d'éventuelles incompatibilités

Entreposez dans un endroit sec et couvert. Minimisez la génération de poussières en suspension dans l'air et évitez leur dispersion par le vent pendant le chargement et le déchargement. Maintenez les conteneurs fermés et stockez les produits emballés de manière à éviter tout éclatement accidentel.

### 7.3. Utilisation(s) finale(s) particulière(s)

Pour plus d'informations, consulter le Scénario d'exposition joint.

Mode D'Emploi

Si vous avez besoin de conseils sur des utilisations spécifiques, contactez votre fournisseur ou consultez le Guide de bonnes pratiques auquel il est fait référence à la section 16.

## SECTION 8: CONTRÔLES DE L'EXPOSITION/PROTECTION INDIVIDUELLE

### 8.1. Paramètres de contrôle

Appellation	NORME	VME - 8 Hrs		VLE - 15 Min		Obs.
Cristobalite	VLEP		0,05 mg/m <sup>3</sup>			
poussières inorganiques	VLEP		5 mg/m <sup>3</sup> poussière respirable			

VLEP = Valeurs limites d'exposition professionnelle.

DDSE

Industrie	Inhalation.	Long terme	0.33	mg/m <sup>3</sup>
Consommateur	Inhalation.	Long terme	0.08	mg/m <sup>3</sup>
Consommateur	Oral	Long terme	3.5	mg/kg/jour

CPSE

ITER	NOAEL value AF=100
Sédiment	n/a
Eau	n/a

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## 8.2. Contrôles de l'exposition

### Mesures d'ingénierie

Se référer aux scénarios d'exposition en Annexe 1 et Section 7. Minimisez la génération de poussières en suspension dans l'air. Utilisez des enceintes de travail, des systèmes d'aspiration locaux ou tout autre forme de dispositif de sécurité intégrée pour conserver les niveaux de matières en suspension en deçà des limites d'exposition spécifiées. Si les opérations utilisateur génèrent des poussières, des fumées ou des brouillards, utilisez un système de ventilation pour maintenir l'exposition aux particules en suspension dans l'air en deçà de la limite d'exposition. Mettez en place des mesures organisationnelles, p. ex. en isolant le personnel des zones poussiéreuses. Retirez et lavez les habits sales. .

### Protection respiratoire

En cas d'exposition prolongée aux concentrations de poussières en suspension dans l'air, portez un équipement de protection respiratoire conforme aux exigences de la législation européenne ou nationale.

### Protection des mains

Porter des gants de protection appropriés en cas de contact prolongé ou répété avec la peau. Les gants de protection en PVC ou caoutchouc sont recommandés.

### Protection des yeux

Utiliser une protection oculaire. Il est recommandé de porter des lunettes de protection et un masque facial. Évitez le port de lentilles de contact lors de l'utilisation de ce produit.

### Mesures d'hygiène

Ne pas manger, boire ou fumer pendant l'utilisation. Se laver après le travail et avant de manger, de fumer et avant d'aller aux toilettes. Utiliser une crème mains appropriée pour éviter un dessèchement de la peau.

### Protection de la peau

Aucune exigence spécifique. Il est recommandé que les travailleurs souffrant de dermatoses ou dont la peau est sensible utilisent des protections appropriées (p. ex. vêtements de protection, crème barrière).

### Contrôle d'exposition lié

à la protection de l'environnement

Traiter les déchets conformément aux réglementations locales et nationales.

## SECTION 9: PROPRIÉTÉS PHYSIQUES ET CHIMIQUES

### 9.1. Informations sur les propriétés physiques et chimiques essentielles

Aspect	Poudre
Couleur	Blanc / blanc cassé.
Odeur	Presque sans odeur.
Solubilité	Insoluble dans l'eau EU Method A6
Point initial d'ébullition et intervalle d'ébullition (°C)	Non applicable.
Point de fusion (°C)	> 450 Méthode A1 de l'EU
Densité relative	2.4 OECD 109
Pression de vapeur	Non applicable.
Valeur pH, Solution Concentrée	Non applicable.
Viscosité	Non applicable.
Température de décomposition (°C)	Non applicable.
Point d'éclair (°C)	Non applicable.
Température d'auto-inflammation (°C)	Non applicable.
Limite D'Inflammabilité - Inférieure (%)	Non applicable.
Limite D'Inflammabilité - Supérieure (%)	Non applicable.
Coefficient De Partage (N-Octanol/Eau)	Non applicable.
Propriétés comburantes	Sans objet

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## **9.2. Autres informations**

Aucune.

## **SECTION 10: STABILITÉ ET RÉACTIVITÉ**

### **10.1. Réactivité**

Aucun risque particulier de réactivité n'est associé à ce produit.

### **10.2. Stabilité chimique**

Stable à température normale et l'emploi recommandé.

### **10.3. Possibilité de réactions dangereuses**

Non applicable.

### **10.4. Conditions à éviter**

Pas d'incompatibilité particulière.

### **10.5. Matières incompatibles**

Matières À Éviter

Pas de groupe d'incompatibilité noté.

### **10.6. Produits de décomposition dangereux**

Aucunes dans les conditions normales.

## **SECTION 11: INFORMATIONS TOXICOLOGIQUES**

### **11.1. Informations sur les effets toxicologiques**

#### Toxicité aiguë:

Toxicité aiguë (DL50 orale)

> 2000 mg/kg Rat

OECD 401

Toxicité aiguë (DL50 dermique)

Non applicable.

Toxicité aiguë (CL50 par inhalation)

> 2.6 mg/l (poussière/brouillard) Rat

OECD 403

#### Corrosion cutanée/irritation cutanée:

Dose Lapin

Dose

Lapin

OECD 404

Aucune irritation.

#### Lésions oculaires graves/irritation oculaire:

Non applicable. Non irritant. OECD 405

#### Sensibilisation respiratoire ou cutanée:

Sensibilisation cutanée

Non applicable. Cobaye

OECD 429

Non sensibilisant.

#### Mutagénicité sur les cellules germinales:

Génotoxicité - In Vitro

Non applicable.

OECD 471. OECD 473. OECD 476.

Négatif.

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## Cancérogénicité:

Cancérogénicité  
Non applicable.

## Toxicité pour la reproduction:

Toxicité pour la reproduction - Fertilité  
Non applicable.

## Toxicité spécifique pour certains organes cibles — exposition unique:

STOT - Une seule exposition  
Non applicable.

## Informations générales

Ce produit a une faible toxicité. Seuls de grandes quantités peuvent avoir un effet néfaste sur la santé humaine.

## Inhalation

Aucun effet sévère n'a été observé lors des études chez l'animal après exposition sévère par inhalation. Une étude sur 90 jours à doses répétées a été proposée. La terre diatomée calcinée (Kieselguhr) contient de la silice cristalline, qui est une cause connue de silicose, une maladie des poumons progressive, parfois létale. Dans une monographie de 1997 (Volume 68, "Silica, Some Silicates, Coal Dust and Para-aramid Fibrils", ), l'Agence Internationale de Recherche sur le Cancer (IARC) a classé la « silice cristalline inhalée au travail » dans le Groupe 1 des substances cancérigènes pour l'homme. Lors de l'évaluation globale, le groupe d'étude de l'IARC a remarqué que la cancérogénicité pour l'homme n'était pas détectée dans tous les cas industriels étudiés. La silice cristalline a aussi été classée cancérigène pour l'homme par la Commission MAK Allemande (Catégorie A1) Les poussières en grandes concentrations peuvent irriter l'appareil respiratoire.

## Ingestion

Aucun effet nocif connu en cas d'ingestion de quantités susceptibles d'être ingérées accidentellement. Aucun effet secondaire sévère ou à long terme n'a été observé lors des études chez l'animal après exposition orale.

## Contact avec la peau

Aucun effet secondaire sévère n'a été observé lors des études chez l'animal après exposition cutanée. La silice amorphe calcinée Kieselguhr n'est pas un irritant pour la peau. Un contact prolongé peut entraîner une peau sèche.

## Contact avec les yeux

La silice amorphe calcinée Kieselguhr n'est pas un irritant pour les yeux.

## Mises En Garde Sur La Santé

Une exposition prolongée et/ou massive aux poussières contenant de la silice cristalline alvéolaire peut provoquer la silicose, une fibrose pulmonaire nodulaire due au dépôt dans les poumons de fines particules alvéolaires de silice cristalline.

En 1997, le CIRC (le Centre international de recherche sur le cancer) a conclu que la silice cristalline inhalée sur le lieu de travail pouvait provoquer un cancer des poumons chez l'homme. Il a toutefois signalé qu'il ne fallait en aucun cas incriminer toutes les circonstances industrielles et tous les types de silice cristalline. (Monographies du CIRC sur l'évaluation des risques carcinogènes des substances chimiques pour les hommes, Silice, poussières de silicates et fibres organiques, 1997, Vol. 68, CIRC, Lyon, France).

En juin 2003, le CSLEP (le Comité scientifique européen en matière de limites d'exposition professionnelle) a conclu que le principal effet pour l'homme de l'inhalation de poussières de silice cristalline alvéolaire était la silicose. "Nous disposons de suffisamment d'informations pour conclure que le risque relatif de cancer du poumon augmente chez les personnes souffrant de silicose (et, apparemment, pas chez les employés ne souffrant pas de silicose, et exposés à des poussières de silice dans les carrières et dans l'industrie de la céramique). La prévention de la survenue de la silicose permettra donc également de réduire le risque de cancer..." (CSLEP, SUM Doc 94-final, juin 2003).

Il existe donc un ensemble de preuves qui confirment le fait que le risque accru de cancer serait limité aux personnes déjà atteintes de silicose. La protection des travailleurs contre la silicose doit être garantie par le respect des limites d'exposition professionnelle réglementaires en vigueur et la mise en œuvre de mesures supplémentaires de gestion des risques, le cas échéant (voir section 16 ci-après).

## SECTION 12: INFORMATIONS ÉCOLOGIQUES

### Écotoxicité

Les composants du produit ne sont pas classés comme dangereux pour l'environnement. Cependant, on ne peut pas exclure la possibilité d'effets nocifs ou dangereux pour l'environnement des déversements majeurs ou fréquents.

### **12.1. Toxicité**

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Toxicité aiguë - Poissons  
96 heures Onchorhynchus mykiss (Truite arc-en-ciel)  
OECD 203  
Toxicité aiguë - invertébrés aquatiques  
48 heures Daphnia magna  
Dépasse la solubilité maximum du produit OECD 202  
Toxicité aiguë - Plantes aquatiques  
72 heures Desmodium subspicatus  
Dépasse la solubilité maximum du produit OECD 201  
Toxicité aiguë - Micro-organismes  
3 heures > 1000 mg/l Boue activée  
Inoffensif pour les microorganismes STP OECD 209

## **12.2. Persistance et dégradabilité**

Dégradabilité

Ce produit contient seulement des composés inorganiques qui ne sont pas biodégradables.

## **12.3. Potentiel de bioaccumulation**

Potentiel de bio-accumulation

Ce produit ne contient pas de substances dont on s'attend un effet de bio-accumulation.

Coefficient de partage

Non applicable.

## **12.4. Mobilité dans le sol**

Mobilité :

Non pertinent dû à la forme du produit. Le produit est insoluble dans l'eau.

## **12.5. Résultats des évaluations PBT et vPvB**

Non classifié dans la catégorie PBT/vPvB selon les critères actuels de l'UE.

## **12.6. Autres effets néfastes**

Pas connu.

## **SECTION 13: CONSIDÉRATIONS RELATIVES À L'ÉLIMINATION**

Informations générales

Peut être éliminé en tant que produit non toxique/inactif dans des sites de décharge agréés selon la législation locale en vigueur. La formation de poussières résultant des résidus présents dans les emballages doit être évitée et la protection adaptée des travailleurs doit être garantie. Stockez les emballages utilisés dans des réceptacles fermés. Le recyclage et l'élimination des emballages doivent être effectués dans le respect des réglementations locales. La réutilisation des emballages n'est pas recommandée. Le recyclage et l'élimination des emballages doivent être effectués par une société de gestion des déchets habilitée.

### **13.1. Méthodes de traitement des déchets**

Dans la mesure du possible, le recyclage est à préférer à l'élimination. Peut être éliminé dans le respect des réglementations locales.

## **SECTION 14: INFORMATIONS RELATIVES AU TRANSPORT**

Généralités

Aucune précaution spéciale. Le produit n'est pas soumis à la réglementation internationale sur le transport des marchandises dangereuses (IMDG, ICAO/IATA, ADR/RID).

### **14.1. Numéro ONU**

Aucune information requise.

### **14.2. Nom d'expédition des Nations unies**

Aucune information requise.

### **14.3. Classe(s) de danger pour le transport**

Aucune information requise.

### **14.4. Groupe d'emballage**

Aucune information requise.

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## 14.5. Dangers pour l'environnement

Substance Dangereuse Pour L'Environnement/Polluant Marin

Non.

## 14.6. Précautions particulières à prendre par l'utilisateur

Non applicable.

## 14.7. Transport en vrac conformément à l'annexe II de la convention Marpol 73/78 et au recueil IBC

Aucune information requise.

## SECTION 15: INFORMATIONS RÉGLEMENTAIRES

### 15.1. Réglementations/législation particulières à la substance ou au mélange en matière de sécurité, de santé et d'environnement

Législation UE

Directive sur les substances dangereuses 67/548/CEE.

Législations nationales

- Le Décret n° 50.1289 du 16 Octobre 1950, modifié par le Décret n° 63.576 du 11 Juin 1963, établit des mesures médicales préventives spéciales pour la silicose au travail.
- La circulaire n° 11453 du 19 Juillet 1982 établit les niveaux de concentrations dans l'air acceptables sur les lieux de travail.
- Décret n° 87-200 du 25 Mars 1987 sur les fiches techniques de sécurité pour les substances dangereuses.
- Article L 231-6 du Code du Travail - Décret du 10 Octobre 1983, modifié par le Décret du 28 Novembre 1984 qui liste les substances dangereuses et établit les conditions d'emballage et d'étiquetage.

### 15.2. Évaluation de la sécurité chimique

Une évaluation de la sécurité chimique a été effectuée.

## SECTION 16: AUTRES INFORMATIONS

Abréviations et acronymes utilisés dans la fiche de données de sécurité

AF = Facteur d'évaluation

BCF = Facteur de bioconcentration

CAS = Service du registre CAS

C & L = Classement et Étiquetage

RCS = Silice cristalline respirable

DNEL = Concentration dérivée sans effet

LC50 = Concentration létale moyenne

LD50 = Dose létale médiane

EC = Commission Européenne

NOAEL = Niveau auquel aucun effet secondaire n'est observé

PBT = Persistant bio-accumulatif toxique

PEC = Concentration effective prévue

PNEC = Concentration prévue sans effet

SDS = Fiche technique de sécurité

STOT = Toxicité spécifique pour organes cibles

STP = Station d'épuration

vPvB = Très persistant très bio-accumulatif

Informations générales

Les travailleurs doivent être informés de la présence de silice cristalline et formés à son utilisation appropriée et à la manipulation de ce produit, conformément aux réglementations en vigueur.

Un accord de dialogue social plurisectoriel sur la protection de la santé des travailleurs dans le cadre de la manipulation et de l'utilisation de la silice cristalline et des produits qui en contiennent a été signé le 25 avril 2006. Cet accord autonome soutenu financièrement par la Commission européenne est fondé sur un Guide de bonnes pratiques. Les exigences de cet accord sont entrées en vigueur depuis le 25 octobre 2006. Cet accord a été publié dans le Journal officiel de l'Union européenne (2006/C 279/02). Le texte de l'accord et de ses annexes ainsi que le Guide de bonnes pratiques, sont disponibles sur le site : <http://www.nepsi.eu> et contiennent des informations et des conseils utiles pour la manipulation des produits qui contiennent de la silice cristalline alvéolaire. Documents de référence disponibles sur demande auprès de EUROSIL, l'Association européenne des producteurs de silice.



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Les informations ci-dessus décrivent exclusivement les conditions de sécurité pour le produit sur la base de nos connaissances actuelles. Les informations ont pour but de vous donner des conseils de précaution lors de la manipulation du produit indiqué dans cette fiche technique de sécurité, pour le stockage, le traitement, le transport et l'élimination. Les informations ne peuvent pas être appliquées à d'autres produits. Si le produit est mélangé à d'autres produits ou traité, les informations contenues dans cette fiche technique de sécurité ne sont pas nécessairement applicables au nouveau produit formé.

Dans la mesure où des produits qui ne sont pas fabriqués ou fournis par (le fabricant) sont utilisés conjointement avec, ou à la place du produit fourni par (le fabricant), le client est responsable d'obtenir du fabricant ou du fournisseur, toutes les données techniques et autres propriétés de ces matériaux et d'obtenir toutes les informations qui s'y rapportent. Aucune responsabilité ayant trait à l'utilisation de la silice amorphe calcinée Kieselguhr (le fabricant) conjointement avec les produits d'un autre fournisseur ne peut être acceptée.

Date de révision 01/12/2013

Révision 8

Phrases - R (Texte Intégral)

NC Non classé.

Mentions De Danger Completes

## Avis De Non-Responsabilité

Ces informations sont conformes aux connaissances de IMERYS et considérées précises et fiables à la date indiquée. Cependant, aucune représentation, aucun engagement ou aucune garantie ne sauraient être exigés pour ce qui concerne leur précision, leur fiabilité ou leur intégrité. L'utilisateur est responsable de s'assurer de l'adaptation et de l'intégrité de ces informations pour l'utilisation visée.

Annex I

## Exposure Scenario 1: Manufacture of Kieselguhr soda ash flux-calcined

<b>1. Short title of exposure scenario 1</b>	
Manufacture of Kieselguhr soda ash flux-calcined	
<b>2. Description of activities and processes covered in the exposure scenario</b>	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites
Product category (PC)	PC 0: (adsorbent, filling material) PC 14: Metal surface treatment products, including galvanic and electroplating products (This covers substances permanently binding with the metal surface)
Process category (PROC)	PROC 2: Use in closed, continuous process with occasional controlled exposure. PROC 3: Use in closed batch process PROC 4: Use in batch or other process where opportunity for exposure arises. Industrial setting PROC 8b: 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).
Article category (AC)	Not applicable
Environmental release category (ERC)	ERC 1: Manufacture of substances
<b>3. Operational conditions</b>	
<b>3.1 Operational conditions related with frequency and quantities of use</b>	
Duration of exposure at workplace:	8 hours per day
Frequency of exposure at workplace:	5 days/week for each worker
Annual amount used per site:	The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario
<b>3.2 Operational conditions related with substance/ product</b>	
Physical state	Solid ranging from a fine powder with high dustiness to coarser granules with low dustiness
Concentration of substance	100% w/w

in mixture	
<b>3.3 Other relevant operational conditions</b>	
No information about frequency and duration of the various tasks is available.	
<b>4. Risk Management Measures</b>	
<b>4.1 RMMs related to workers</b>	
Organisational measures	Local exhaust ventilation is installed at manufacturing sites. The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	Safe conditions were defined by taking into account local exhaust ventilation in the present scenario
Respiratory protection	Workers may use half-face masks (P2 or P3) with an efficiency of at least 90% in situations with elevated dust concentrations in the air.
Hand protection	Workers use gloves during the handling of the pure, solid substance
Eye protection	Workers use safety glasses during the handling of the pure, solid substance
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
<b>4.2 RMMs related to the environment</b>	
Organisational measures	Waste gases are cleaned by passage through cyclones or scrubber units or by filtration with bag filters. Solid and liquid wastes are disposed of in landfills or may be incinerated
Abatement measures related with wastewater	The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more.
Abatement measures waste air and solid waste	It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas.
<b>4.3 Waste related measures</b>	
Type of waste	Solid and liquid waste
Disposal technique	Solid and liquid wastes are disposed of in landfills or may be incinerated.
Fraction released to environment during waste treatment	Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution).
<b>5. Prediction of exposure resulting from the conditions described above and the substance properties.</b>	
<b>5.1. Human exposure</b>	
Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation)	The workers' inhalation exposure to kieselguhr soda ash flux-calcined is estimated with the ECETOC TRA tool (ECETOC 2010). The assessment of exposure concentrations was performed with the three grades of dustiness that can be selected in the TRA tool: low, medium and high. The

*DNEL: Worker, long-term, systemic, inhalation: 0.33 mg/m<sup>3</sup>*

modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in the table for all activities. It is concluded that the manufacture of solid kieselguhr soda ash flux-calcined exhibiting different grades of dustiness is safe for workers under the specified conditions of exposure. This applies also to storage, repackaging and distribution of the substance. Safe conditions were defined by taking into account local exhaust ventilation in the present scenario. To achieve acceptable airborne concentrations of kieselguhr soda ash flux-calcined the efficiency of LEV and the duration of exposure were modified. Safe conditions can also be achieved by the use of personal respiratory equipment in addition or as an alternative to LEV. Consequently, the presentation of safe conditions is not exhaustive in the present ES.

Process Category	LEV	Duration	PRE	Content (%)	Inhalation exposure (mg/m <sup>3</sup> )	RCR
<b>INDUSTRIAL USE WITH SUBSTANCE EXHIBITING HIGH DUSTINESS</b>						
1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	100	0.01	0.028
2 – Use in closed, continuous process with occasional controlled exposure	90%	4 to 8	No	100	0.1	0.278
3 – Use in closed batch process (synthesis or formulation)	90%	4 to 8	No	100	0.1	0.278
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	95%	Up to 1	No	100	0.25	0.694
5 – Mixing or blending in batch processes (multistage and/or significant contact)	95%	Up to 1	No	100	0.25	0.694
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	95%	Up to 1	No	100	0.25	0.694
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	95%	Up to 1	No	100	0.25	0.694
9 – Transfer of chemicals into small containers (dedicated filling line)	95%	Up to 1	No	100	0.2	0.556
15 – Use of laboratory reagents in small scale laboratories	95%	4 to 8	No	100	0.25	0.694
19 – Hand-mixing with intimate contact (only PPE available)	95%	Up to 1	No	100	0.25	0.694
<b>INDUSTRIAL USE WITH SUBSTANCE EXHIBITING MEDIUM DUSTINESS</b>						
1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	100	0.01	0.028
2 – Use in closed, continuous process with occasional controlled exposure	90%	4 to 8	No	100	0.1	0.278
3 – Use in closed batch process (synthesis or formulation)	80%	4 to 8	No	100	0.2	0.556
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	95%	4 to 8	No	100	0.25	0.694
5 – Mixing or blending in batch processes (multistage and/or significant contact)	95%	4 to 8	No	100	0.25	0.694
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	95%	4 to 8	No	100	0.25	0.694
8b – Transfer of chemicals	95%	4 to 8	No	100	0.25	0.694

	from/to vessels/ large containers at dedicated facilities						
	9 – Transfer of chemicals into small containers (dedicated filling line)	95%	4 to 8	No	100	0.25	0.694
	15 – Use of laboratory reagents in small scale laboratories	50%	4 to 8	No	100	0.25	0.694
	19 – Hand-mixing with intimate contact (only PPE available)	95%	4 to 8	No	100	0.25	0.694
<b>INDUSTRIAL USE WITH SUBSTANCE EXHIBITING LOW DUSTINESS</b>							
	1 – Use in closed process, no likelihood of exposure	No	4 to 8	No	100	0.01	0.028
	2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	100	0.01	0.028
	3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	100	0.1	0.278
	4 – Use in batch and other process (synthesis) where opportunity for exposure arises	50%	4 to 8	No	100	0.25	0.694
	5 – Mixing or blending in batch processes (multistage and/or significant contact)	50%	4 to 8	No	100	0.25	0.694
	8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	50%	4 to 8	No	100	0.25	0.694
	8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	No	4 to 8	No	100	0.1	0.278
	9 – Transfer of chemicals into small containers (dedicated filling line)	No	4 to 8	No	100	0.1	0.278
	15 – Use of laboratory reagents in small scale laboratories	No	4 to 8	No	100	0.1	0.278
	19 – Hand-mixing with intimate contact (only PPE available)	50%	4 to 8	No	100	0.25	0.694
Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.						
Indirect exposure via the environment	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.						
Consumer exposure	No direct consumer exposure is resulting from the manufacture of kieselguhr soda ash flux-calcined.						
<b>5.2. Environmental exposure (qualitative assessment)</b>							
Waste water treatment plants (WWTP)	According to unpublished monitoring data, wastewater released at manufacturing sites may contain up to 100 mg kieselguhr soda ash flux-calcined per litre. This is exceeding the amount that can be dissolved in one litre of water at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering the local sewage treatment plant (STP), the wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of kieselguhr soda ash flux-calcined. The sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation						

	of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out.
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux-calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the manufacture of the substance and waste air is expected to be filtered before released to the environment. ed WAS. The atmospheric concentrations of the substance are expected to be low. It is recommended to pass waste gas from manufacturing processes through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas. No further assessment of the exposure concentrations in the atmosphere is undertaken.
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

## Exposure Scenario 2: Use as filter aid in industrial settings

<b>1. Short title of exposure scenario 2</b>	
<b>Use as a filter aid in industrial settings</b>	
<b>2. Description of activities and processes covered in the exposure scenario</b>	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites SU 4: Manufacture of food products SU 6: Manufacture of pulp, paper and paper products SU 8: Manufacture of bulk, large scale chemicals SU 10: Formulation mixing) of preparations and/or re-packaging SU 14: Manufacture of basic metals SU 17: General manufacturing, eg machner, equipment, vehicles, other transport equipment
Product category (PC)	PC 2: Adsorbents PC 14: Metal surface treatment products, including galvanic and electroplating products PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 25: Metal working fluids PC 35: Washing and cleaning products (including solvent based products) PC 0: Other: Filtration material
Process category (PROC)	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available.
Article category (AC)	Not applicable
Environmental release category (ERC)	ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 6b: Industrial use of reactive processing aids ERC 7: Industrial use of substances in closed systems
<b>3. Operational conditions</b>	
<b>3.1 Operational conditions related with frequency and quantities of use</b>	
Duration of exposure at workplace:	4-8 hours per day
Frequency of exposure at	5 days/week for each worker

workplace:	
Annual amount used per site:	The daily and annual amount/emission per site is not considered to be the main determinant for environmental exposure.
<b>3.2 Operational conditions related with substance/ product</b>	
Physical state	Solid and liquid
Concentration of substance in mixture	A concentration of 100% w/w was used to assess exposure to the solid substance. The exposure concentrations due to contact with liquid mixtures were calculated by taking into account a concentration of the substance in the liquid phase ranging from 5% to 25%.
<b>3.3 Other relevant operational conditions</b>	
No information about frequency and duration of the various tasks is available.	
<b>4. Risk Management Measures</b>	
<b>4.1 RMMs related to workers</b>	
Organisational measures	Solid substance: Local exhaust ventilation is installed at the manufacturing sites. The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	Solid substance: Safe conditions were defined by taking into account local exhaust ventilation in the present scenario  Liquid substance: Outdoor activity – natural ventilation
Respiratory protection	In addition, workers may use half-face masks (P2 or P3) with an efficiency of at least 90% in situations with elevated dust concentrations in the air.  Liquid substance: N/A
Hand protection	Skin protection may be used.
Eye protection	Eye protection may be used.
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
<b>4.2 RMMs related to the environment</b>	
Organisational measures	Waste gases are cleaned by passage through cyclones or scrubber units or by filtration with bag filters. Solid and liquid wastes are disposed of in landfills or may be incinerated
Abatement measures related with wastewater	The wastewater can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more.
Abatement measures waste air and solid waste	Waste air may be filtered eg by bag filters or scrubber units.
<b>4.3 Waste related measures</b>	
Type of waste	Solid and liquid waste.
Disposal	Solid and liquid waste may be incinerated or disposed of in landfills.



technique																																																																														
Fraction released to environment during waste treatment	Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution).																																																																													
<b>5. Prediction of exposure resulting from the conditions described above and the substance properties.</b>																																																																														
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Workers (oral)	Good hygiene practice will minimise oral exposure																																																																													
Workers (inhalation) <i>DNEL: Worker, long-term, systemic, inhalation: 0.33 mg/m<sup>3</sup></i>	<p>Safe conditions for the handling of solid kieselguhr soda ash flux-calcined are given in for the manufacture of the substance. These apply also to the use of the substance as filter aid covered in exposure scenario 2. The modelled long-term exposure concentrations resulting from the handling of liquid mixtures containing the substance are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in <b>Error! Reference source not found.</b> for all activities described in exposure scenario 1. It is concluded that the manufacture of solid kieselguhr soda ash flux-calcined exhibiting different grades of dustiness is safe for workers under the specified conditions of exposure.</p> <table border="1"> <thead> <tr> <th>Process Category</th> <th>LEV</th> <th>Duration</th> <th>PRE</th> <th>Content (%)</th> <th>Inhalation exposure (mg/m<sup>3</sup>)</th> <th>RCR</th> </tr> </thead> <tbody> <tr> <td colspan="7" style="text-align: center;">INDUSTRIAL USE OF LIQUID MATERIAL</td> </tr> <tr> <td>2 – Use in closed, continuous process with occasional controlled exposure</td> <td>No</td> <td>4 to 8</td> <td>No</td> <td>5 to 25</td> <td>0.147</td> <td>0.408</td> </tr> <tr> <td>3 – Use in closed batch process (synthesis or formulation)</td> <td>No</td> <td>4 to 8</td> <td>No</td> <td>5 to 25</td> <td>0.147</td> <td>0.408</td> </tr> <tr> <td>4 – Use in batch and other process (synthesis) where opportunity for exposure arises</td> <td>No</td> <td>4 to 8</td> <td>No</td> <td>5 to 25</td> <td>0.147</td> <td>0.408</td> </tr> <tr> <td>5 – Mixing or blending in batch processes (multistage and/or significant contact)</td> <td>No</td> <td>4 to 8</td> <td>No</td> <td>5 to 25</td> <td>0.147</td> <td>0.408</td> </tr> <tr> <td>8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities</td> <td>No</td> <td>4 to 8</td> <td>No</td> <td>5 to 25</td> <td>0.147</td> <td>0.408</td> </tr> <tr> <td>8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities</td> <td>No</td> <td>4 to 8</td> <td>No</td> <td>5 to 25</td> <td>0.147</td> <td>0.408</td> </tr> <tr> <td>9 – Transfer of chemicals into small containers (dedicated filling line)</td> <td>No</td> <td>4 to 8</td> <td>No</td> <td>5 to 25</td> <td>0.147</td> <td>0.408</td> </tr> <tr> <td>15 – Use of laboratory reagents in small scale laboratories</td> <td>No</td> <td>4 to 8</td> <td>No</td> <td>5 to 25</td> <td>0.147</td> <td>0.408</td> </tr> <tr> <td>19 – Hand-mixing with intimate contact (only PPE available): modelled with ConsExpo</td> <td>No</td> <td>8</td> <td>No</td> <td>10</td> <td>0.0002</td> <td>0.001</td> </tr> </tbody> </table>	Process Category	LEV	Duration	PRE	Content (%)	Inhalation exposure (mg/m <sup>3</sup> )	RCR	INDUSTRIAL USE OF LIQUID MATERIAL							2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	5 to 25	0.147	0.408	3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	5 to 25	0.147	0.408	4 – Use in batch and other process (synthesis) where opportunity for exposure arises	No	4 to 8	No	5 to 25	0.147	0.408	5 – Mixing or blending in batch processes (multistage and/or significant contact)	No	4 to 8	No	5 to 25	0.147	0.408	8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	No	4 to 8	No	5 to 25	0.147	0.408	8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	No	4 to 8	No	5 to 25	0.147	0.408	9 – Transfer of chemicals into small containers (dedicated filling line)	No	4 to 8	No	5 to 25	0.147	0.408	15 – Use of laboratory reagents in small scale laboratories	No	4 to 8	No	5 to 25	0.147	0.408	19 – Hand-mixing with intimate contact (only PPE available): modelled with ConsExpo	No	8	No	10	0.0002	0.001
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Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.																																																																													
Indirect exposure via the	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low.																																																																													

environment	The substance has a low solubility in water and thus is essentially unavailable to organisms.
Consumer exposure	No direct consumer exposure is resulting from the manufacture of kieselguhr soda ash flux-calcined.
<b>5.2. Environmental exposure (qualitative assessment)</b>	
Waste water treatment plants (WWTP)	The amount of kieselguhr soda ash flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering a sewage treatment plant (STP), the wastewater should be treated by sedimentation to remove the greatest portion of solids. Sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of kieselguhr soda ash flux-calcined as a filter aid in industrial settings. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

## Exposure Scenario 3: Use as additive in formulation of liquid, viscous or solid mixtures

<b>1. Short title of exposure scenario 3</b>	
<b>Use as an additive in formulation of liquids, viscous or solid mixtures</b>	
<b>2. Description of activities and processes covered in the exposure scenario</b>	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites SU 10: Formulation mixing) of preparations and/or re-packaging SU 11: Manufacture of rubber products SU 13: Manufacture of other non-metallic mineral products, eg plasters, cement
Product category (PC)	PC 2: Adsorbents PC 9: Coatings and paints, fillers, putties, thinners PC 21: Laboratory chemicals PC 29: Pharmaceuticals PC 35: Washing and cleaning products (including solvent based products)
Process category (PROC)	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available.
Article category (AC)	AC 10: Rubber products AC 13: Plastic products
Environmental release category (ERC)	ERC 2: Formulation of preparations ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 7: Industrial use of substances in closed systems ERC 8b: Wide dispersive indoor use of reactive substances in open systems
<b>3. Operational conditions</b>	
<b>3.1 Operational conditions related with frequency and quantities of use</b>	
Duration of exposure at workplace:	8 hours per day
Frequency of exposure at workplace:	5 days/week for each worker
Annual amount used per site:	The daily and annual amount/emission per site is not considered to be the main determinant for environmental exposure.

<b>3.2 Operational conditions related with substance/ product</b>	
Physical state	Solid and liquid
Concentration of substance in mixture	The concentration of the substance in the final mixtures may range from <1 % (liquid) to 60 % (dental fillings).
<b>3.3 Other relevant operational conditions</b>	
No information about frequency and duration of the various tasks is available.	
<b>4. Risk Management Measures</b>	
<b>4.1 RMMs related to workers</b>	
Organisational measures	The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	LEV may be present and/or respiratory masks (P3) may be used in situations with elevated dust concentrations in the air. Skin protection and eye protection may be used
Respiratory protection	LEV may be present and/or respiratory masks (P3) may be used in situations with elevated dust concentrations in the air.
Hand protection	Skin protection may be used.
Eye protection	Eye protection may be used.
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
<b>4.2 RMMs related to the environment</b>	
Organisational measures	Waste gases are cleaned by passage through cyclones or scrubber units or by filtration with bag filters. Solid and liquid wastes are disposed of in landfills or may be incinerated
Abatement measures related with wastewater	The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more.
Abatement measures waste air and solid waste	It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas.
<b>4.3 Waste related measures</b>	
Type of waste	Solid and liquid waste.
Disposal technique	Solid and liquid waste may be incinerated or disposed of in landfills.
Fraction released to environment during waste treatment	Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution).
<b>5. Prediction of exposure resulting from the conditions described above and the substance properties.</b>	

<b>5.1. Human exposure</b>	
Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation) <i>DNEL: Worker, long-term, systemic, inhalation: 0.36mg/m<sup>3</sup></i>	The workers' inhalation exposure to kieselguhr soda ash flux-calcined that may occur during the formulation of liquid, viscous or solid preparations described in the present exposure scenario ES 3 is covered by the exposure concentrations calculated in the exposure scenarios ES 1 and ES 2.
Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via the environment	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.
Consumer exposure	No direct consumer exposure is resulting from the use of kieselguhr soda-ash flux calcined as an additive in the formulation of liquid, viscous or solid mixtures.
<b>5.2. Environmental exposure (qualitative assessment)</b>	
Waste water treatment plants (WWTP)	The amount of kieselguhr soda ash flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering a sewage treatment plant (STP), the wastewater should be treated by sedimentation to remove the greatest portion of solids. Sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken

Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of kieselguhr soda ash flux-calcined as a filter aid in industrial settings. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

## Exposure Scenario 4: Use as process aid in manufacture of chemicals, resins, rubbers and plastics

<b>1. Short title of exposure scenario 4</b>	
<b>Use as an additive in formulation of liquids, viscous or solid mixtures</b>	
<b>2. Description of activities and processes covered in the exposure scenario</b>	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites SU 8: Manufacture of bulk, large scale chemicals SU 9: Manufacture of fine chemicals SU 11: Manufacture of rubber products SU 12: Manufacture of plastics products, including compound and conversion .
Product category (PC)	PC 16: Heat transfer fluids PC 17: Hydraulic fluids PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 24: Lubricants, greases, release products PC 25: Metal working fluids PC 32: Polymer preparations and compounds
Process category (PROC)	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available.
Article category (AC)	Not applicable
Environmental release category (ERC)	ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles
<b>3. Operational conditions</b>	
<b>3.1 Operational conditions related with frequency and quantities of use</b>	
Duration of exposure at workplace:	8 hours per day
Frequency of exposure at workplace:	360 days/year for each worker

Annual amount used per site:	The daily and annual amount/emission per site is not considered to be the main determinant for environmental exposure.
<b>3.2 Operational conditions related with substance/ product</b>	
Physical state	Solid and liquid
Concentration of substance in mixture	100% w/w
<b>3.3 Other relevant operational conditions</b>	
No information about frequency and duration of the various tasks is available.	
<b>4. Risk Management Measures</b>	
<b>4.1 RMMs related to workers</b>	
Organisational measures	The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	LEV may be present and/or respiratory masks (P3) may be used in situations with elevated dust concentrations in the air. Skin protection and eye protection may be used
Respiratory protection	LEV may be present and/or respiratory masks (P3) may be used in situations with elevated dust concentrations in the air.
Hand protection	Skin protection may be used.
Eye protection	Eye protection may be used.
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.
<b>4.2 RMMs related to the environment</b>	
Organisational measures	Not applicable
Abatement measures related with wastewater	The wastewater resulting from manufacturing of the substance can be treated by sedimentation to remove the solid parts of the substance. The sedimentation is very efficient with a reduction efficacy of 99% or more.
Abatement measures waste air and solid waste	It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas.
<b>4.3 Waste related measures</b>	
Type of waste	Solid and liquid waste.
Disposal technique	Solid and liquid waste may be incinerated or disposed of in landfills.
Fraction released to environment during waste treatment	Any wastewater released from the sedimentation step is expected not to contain more than 3.87 mg/L (saturated solution).

<b>5. Prediction of exposure resulting from the conditions described above and the substance properties.</b>	
<b>5.1. Human exposure</b>	
Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation) <i>DNEL: Worker, long-term, systemic, inhalation: 0.36mg/m<sup>3</sup></i>	The workers' inhalation exposure to kieselguhr soda ash flux-calcined that may occur during the formulation of liquid, viscous or solid preparations described in the present exposure scenario ES 4 is covered by the exposure concentrations calculated in the exposure scenarios ES 1 and ES 2.
Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via the environment	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.
Consumer exposure	No direct consumer exposure is resulting from the use of kieselguhr soda ash flux-calcined as a process aid in the manufacture of chemicals, resins, rubbers and plastics
<b>5.2. Environmental exposure (qualitative assessment)</b>	
Waste water treatment plants (WWTP)	The amount of kieselguhr soda ash flux-calcined present in the wastewater may exceed the amount that can be dissolved at saturation (3.87 mg/L at 20°C), indicating that suspended particles of kieselguhr soda ash flux-calcined may be present in the wastewater. Before entering a sewage treatment plant (STP), the wastewater should be treated by sedimentation to remove the greatest portion of solids. Sedimentation is very efficient with a reduction efficacy of 99% or more. Any wastewater released from the sedimentation step is expected to contain not more than 3.87 mg kieselguhr soda ash flux-calcined per litre wastewater (saturated solution). No further degradation of the substance in the course of wastewater treatment is taken into account in the present assessment and the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in the effluent of a local STP is 3.87 mg/L.
Aquatic pelagic compartment	To calculate the reasonable worst-case concentration of kieselguhr soda ash flux-calcined in surface water that may be due to emissions from the manufacture of the substance, the concentration of 3.87 mg/L in the effluent of the local STP is taken and a dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water (default EUSES). This leads to a surface water concentration of 0.387 mg/L. For releases of the wastewater to coastal sites, a dilution factor of 100 (EUSES default) is taken into account which leads to a concentration of 0.0387 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated



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	with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of the substance as a process aid in the manufacture of chemicals, resins, rubbers and plastics. The atmospheric concentrations of the substance are expected to be low. It is recommended to pass waste gas through bag filters, scrubbers or cyclones to reduce the amount of solid substance in the waste gas. No further assessment of the exposure concentrations in the atmosphere is undertaken
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

## Exposure Scenario 5: Professional use by dental technicians and dentists

<b>1. Short title of exposure scenario 4</b>	
<b>Use as an additive in formulation of liquids, viscous or solid mixtures</b>	
<b>2. Description of activities and processes covered in the exposure scenario</b>	
Sector of use (SU)	SU 9: Manufacture of fine chemicals SU 10: Formulation mixing) of preparations and/or re-packaging SU 12: Manufacture of plastics products, including compound and conversion SU 20: Health surfaces
Product category (PC)	PC 32: Polymer preparations and compounds
Process category (PROC)	PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 19: Hand-mixing with intimate contact and only PPE available.
Article category (AC)	Not applicable
Environmental release category (ERC)	ERC 2: Formulation of preparations ERC 3: Formulation in materials ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix
<b>3. Operational conditions</b>	
<b>3.1 Operational conditions related with frequency and quantities of use</b>	
Duration of exposure at workplace:	Up to 1 h/day
Frequency of exposure at workplace:	Performed on up to 220 days/year
Annual amount used per site:	The daily and annual amount emission per site is not considered to be the main determinant for environmental exposure.
<b>3.2 Operational conditions related with substance/ product</b>	
Physical state	Solid and liquid
Concentration of substance in mixture	Such materials can contain the substance at levels up to 60% w/w
<b>3.3 Other relevant operational conditions</b>	
No information about frequency and duration of the various tasks is available.	
<b>4. Risk Management Measures</b>	
<b>4.1 RMMs related to workers</b>	

Organisational measures	The employer has also to ascertain that the required PPE is available and used according to instructions.														
Technical measures	Professionals normally do the mixing in the absence of LEV.														
Respiratory protection	N/A														
Hand protection	Skin protection may be used.														
Eye protection	Eye protection may be used.														
Skin and body protection	Wearing of suitable protective clothing.														
Hygiene measures	Standard occupational hygiene measures should be adopted.														
<b>4.2 RMMs related to the environment</b>															
Organisational measures	Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer. Solid waste may be incinerated or deposited in landfills														
Abatement measures related with wastewater	Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer														
Abatement measures waste air and solid waste	Solid waste may be incinerated or deposited in landfills. Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of the substance in dental practices. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken.														
<b>4.3 Waste related measures</b>															
Type of waste	Solid and liquid waste.														
Disposal technique	Solid waste may be incinerated or deposited in landfills. Any liquid waste that results from cleaning of equipment will be disposed of via the public sewer.														
Fraction released to environment during waste treatment	<p>Emissions from filling and alginate impression material may occur on 260 days per year. About 300 tonnes kieselguhr soda ash flux-calcined are used per year for dental filling and impression material in the EU. A fraction of 10%, i.e. 30 t/year, is considered for regional use. For the local use, 0.2% of the regional tonnage is considered, i.e. 60 kg/year. Part of the substance may be release to the wastewater when cleaning materials which were in contact with preparations containing kieselguhr soda ash flux-calcined. It is expected that at most 10% of the filling and impression materials are released to the sewer, i.e. 6 kg per year on the local scale. This results in a reasonable worst-case emission of substance into the wastewater of 0.023 kg/day. Emissions of the substance into the atmosphere or the soil compartment are negligible</p> <table border="1"> <thead> <tr> <th>Parameter</th> <th>Value</th> </tr> </thead> <tbody> <tr> <td>Tonnage in EU per year</td> <td>300 t</td> </tr> <tr> <td>Regional tonnage per year</td> <td>30 t</td> </tr> <tr> <td>Local tonnage per year</td> <td>60 kg</td> </tr> <tr> <td>Fraction of main local source</td> <td>0.002</td> </tr> <tr> <td>Number of days</td> <td>260 d</td> </tr> <tr> <td></td> <td></td> </tr> </tbody> </table>	Parameter	Value	Tonnage in EU per year	300 t	Regional tonnage per year	30 t	Local tonnage per year	60 kg	Fraction of main local source	0.002	Number of days	260 d		
Parameter	Value														
Tonnage in EU per year	300 t														
Regional tonnage per year	30 t														
Local tonnage per year	60 kg														
Fraction of main local source	0.002														
Number of days	260 d														

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	Fraction of tonnage released to air	0	
	Fraction of tonnage released to wastewater	0.1	
	Fraction of tonnage released to soil	0	
	Local emissions to wastewater	0.023 kg/day	

**5. Prediction of exposure resulting from the conditions described above and the substance properties.**

**5.1. Human exposure**

Workers (oral)	Good hygiene practice will minimise oral exposure
Workers (inhalation) <i>DNEL: Worker, long-term, systemic, inhalation:0.36 mg/m<sup>3</sup></i>	The modelled reasonable worst-case long-term exposure concentrations resulting from the handling of small amounts of dental filling or impression materials (about 50 g/application) is 0.024 mg/m <sup>3</sup> . The RCR obtained by comparing this concentration of the long-term inhalation DNEL of 0.36 mg/m <sup>3</sup> is 0.067 showing that the potential health risk for workers is controlled for the professional use of kieselguhr soda ash flux-calcined as dental filling and impression material by dental technicians and dentists.
Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.
Indirect exposure via the environment	It is expected that emissions of kieselguhr soda ash flux-calcined from its identified uses will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms. It is concluded that indirect human exposure to kieselguhr soda ash flux-calcined via the environment is not relevant
Consumer exposure	Patients may ingest small amounts of substance during dental treatment. In general exposure is expected to be negligible as the dental treatment is performed under professional surveillance.

**5.2. Environmental exposure (qualitative assessment)**

Waste water treatment plants (WWTP)	In the present assessment, the wastewater passes through a sewage treatment plant (STP) which has a capacity of 2000000 L/day. No removal of kieselguhr soda ash flux-calcined during wastewater treatment is taken into account for the present exposure scenario. The resulting reasonable worst-case concentration of the substance in the effluent of a local STP is $23000/2000000=0.012$ mg/L
Aquatic pelagic compartment	A dilution factor of 10 is taken into account at the point of mixing of the wastewater with surface water, leading to a surface water concentration of 0.0012 mg/L. For coastal areas a dilution factor of 100 is taken into account, leading to a concentration of 0.00012 mg/L in marine waters
Sediments	The wastewater released to the environment may contain suspended particles of kieselguhr soda ash flux-calcined. These solid parts will settle down at the bottom of the receiving water. As kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms and is naturally formed in water bodies this not considered to cause a potential hazard to the receiving water. Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out.
Soil and groundwater	Kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release

	of a significant quantity kieselguhr soda ash flux-calcined is expected to alter the physical and chemical characteristics of a soil. As atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of the substance in dental practices. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken
Secondary poisoning	The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms.

## Exposure Scenario 6: Industrial, professional and private use of substance or mixtures containing the substance

<b>1. Short title of exposure scenario 6</b>	
<b>Use as an additive in formulation of liquids, viscous or solid mixtures</b>	
<b>2. Description of activities and processes covered in the exposure scenario</b>	
Sector of use (SU)	SU 3: Industrial uses: uses of substances as such or in preparations at industrial sites SU 21: Consumer uses: Private households (= general public = consumers) SU22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
Product category (PC)	PC 35: Washing and cleaning products (including solvent based products) PC 37: Water treatment chemicals
Process category (PROC)	PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 19: Hand-mixing with intimate contact and only
Article category (AC)	AC 10: Rubber products AC 13: Plastic products
Environmental release category (ERC)	ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8d: Wide dispersive outdoor use of processing aids in open systems ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix ERC 10b: Wide dispersive outdoor use of long-life articles and materials with high or intended release (including abrasive processing)
<b>3. Operational conditions</b>	
<b>3. 1 Operational conditions related with frequency and quantities of use</b>	

Duration of exposure at workplace:	Use of coatings and paints containing kieselguhr soda ash flux-calcined: 4-8 hours Use of kieselguhr soda ash flux calcined for filtering water: Approximately 1 hour per day. Use of cleaners containing kieselguhr soda-ash flux calcined: Professionals up to 60 minutes per use, consumers up to 20 minutes per day.
Frequency of exposure at workplace:	Use of coatings and paints containing kieselguhr soda ash flux-calcined: Up to 225 days per year Use of kieselguhr soda ash flux calcined for filtering water: Weekly for professional use and monthly consumer use Use of cleaners containing kieselguhr soda-ash flux calcined: Professionals up to 8 times a day.
Annual amount used per site:	The daily and annual amount emission per site is not considered to be the main determinant for environmental exposure.

**3.2 Operational conditions related with substance/ product**

Physical state	Solid and liquid
Concentration of substance in mixture	A variety of articles made from rubbers or plastics contain the substance. The average weight fraction of kieselguhr soda ash flux-calcined in such articles is about 7% w/w and the maximum weight fraction is approximately 15% w/w.

**3.3 Other relevant operational conditions**

No information about frequency and duration of the various tasks is available.

**4. Risk Management Measures**

**4.1 RMMs related to workers**

Organisational measures	The employer has also to ascertain that the required PPE is available and used according to instructions.
Technical measures	Safe conditions were defined by considering that workers use respiratory equipment during industrial spraying to protect themselves against elevated airborne concentrations of coatings or paints. Alternatively safe conditions may also be achieved by ensuring very good ventilation in the workplace. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr is expected.
Respiratory protection	If elevated exposure is to be expected LEV may be present and industrial and professional users may wear breathing masks reducing the amount of inhaled aerosols
Hand protection	Skin protection may be used.
Eye protection	Eye protection may be used.
Skin and body protection	Wearing of suitable protective clothing.
Hygiene measures	Standard occupational hygiene measures should be adopted.

**4.2 RMMs related to the environment**

Organisational measures	Kieselguhr soda ash flux-calcined used for the filtering of drinking and swimming pool water and kieselguhr soda ash flux-calcined present in surface cleaners may be released to the sewer and subsequently pass a municipal sewage treatment plant (STP).
Abatement measures related with wastewater	Any liquid waste that results will be disposed of via the public sewer

Abatement measures waste air and solid waste	Solid waste may be disposed of as industrial, commercial or common household waste and may be incinerated or disposed of in landfills Waste air at industrial and professional sites may be filtered before released to the atmosphere.
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**4.3 Waste related measures**

Type of waste	Liquid/solid waste.
Disposal technique	Wastewater that is generated during cleaning operations may be treated in an onsite treatment plant or be released to the public sewer system and treated in a municipal STP. Solid waste may be disposed of as industrial, commercial or common household waste and may be incinerated or disposed of in landfills.
Fraction released to environment during waste treatment	A worst-case is considered in the present assessment in that 10% of the total tonnage placed on the EU market ends up in municipal STPs

**5. Prediction of exposure resulting from the conditions described above and the substance properties.**

**5.1. Human exposure**

Workers (oral)	Good hygiene practice will minimise oral exposure
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Workers (inhalation) <i>DNEL: Worker, long-term, systemic, inhalation 0.36: mg/m<sup>3</sup></i>	The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in exposure scenario 5. Safe conditions for additional activities are shown in the table below Safe conditions were defined by considering that workers use personal respiratory equipment during industrial spraying to protect themselves against elevated airborne concentrations of coatings or paints. Alternatively, safe conditions may also be achieved by ensuring very good ventilation of the workplace. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr soda ash flux-calcined is anticipated. It is concluded that the industrial use of mixtures containing kieselguhr soda ash flux-calcined is safe for workers under the specified conditions of exposure.						
	<b>Safe conditions for industrial activities performed during the use of mixtures containing kieselguhr soda ash flux-calcined</b>						
						Inhalation exposure (mg/m <sup>3</sup> )	
	<b>Process Category</b>	<b>LEV</b>	<b>Duration</b>	<b>PRE</b>	<b>Content (%)</b>		<b>RCR</b>
	<b>INDUSTRIAL USE OF LIQUID MATERIAL</b>						
7 – Industrial spraying based on TNsG (European Commission 2002)	No	Up to 6	95%	10	0.325	0.903	
10 – Roller application or brushing	No	4 to 8	No	5 to 25	0.125	0.347	
13 – Treatment of articles by dipping and pouring	No	4 to 8	No	5 to 25	0.147	0.408	
The modelled long-term exposure concentrations are compared to the DNEL for chronic inhalation exposure to obtain risk characterisation ratios. RCRs above 1 indicate that the potential risk is not adequately controlled. Safe conditions of use are described in the table above. Safe conditions were defined by considering that workers use personal respiratory equipment during non-industrial spraying to protect themselves against elevated airborne concentrations of coatings or paints. Alternatively, safe conditions may also be achieved by ensuring very good ventilation of the							

workplace. The reasonable worst-case airborne concentration of the substance resulting from professional cleaning was 1.86E-05 mg/m<sup>3</sup>. The RCR obtained by comparing this concentration of the long-term inhalation DNEL of 0.36 mg/m<sup>3</sup> is 5.2E-05 showing that the potential health risk for workers is controlled for the professional use of cleaners. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr soda ash flux-calcined is anticipated. It is concluded that the professional use of mixtures containing kieselguhr soda ash flux-calcined is safe for workers under the specified conditions of exposure

Process Category	LEV	Duration	PRE	Content (%)	Inhalation exposure (mg/m <sup>3</sup> )	RCR
<b>PROFESSIONAL USE OF SOLID MATERIAL WITH MEDIUM DUSTINESS</b>						
2 – Use in closed, continuous process with occasional controlled exposure	75%	4 to 8	No	100	0.25	0.694
3 – Use in closed batch process (synthesis or formulation)	75%	4 to 8	No	100	0.25	0.694
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	95%	4 to 8	No	100	0.25	0.694
5 – Mixing or blending in batch processes (multistage and/or significant contact)	95%	4 to 8	No	100	0.25	0.694
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	95%	4 to 8	No	100	0.25	0.694
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	95%	4 to 8	No	100	0.25	0.694
9 – Transfer of chemicals into small containers (dedicated filling line)	95%	4 to 8	No	100	0.25	0.694
19 – Hand-mixing with intimate contact (only PPE available)	95%	4 to 8	No	100	0.25	0.694
<b>PROFESSIONAL USE OF LIQUID MATERIAL</b>						
2 – Use in closed, continuous process with occasional controlled exposure	No	4 to 8	No	5 to 25	0.15	0.417
3 – Use in closed batch process (synthesis or formulation)	No	4 to 8	No	5 to 25	0.15	0.417
4 – Use in batch and other process (synthesis) where opportunity for exposure arises	No	4 to 8	No	5 to 25	0.15	0.417
5 – Mixing or blending in batch processes (multistage and/or significant contact)	No	4 to 8	No	5 to 25	0.15	0.417
8a – Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	No	4 to 8	No	5 to 25	0.15	0.417
8b – Transfer of chemicals from/to vessels/ large containers at dedicated facilities	No	4 to 8	No	5 to 25	0.15	0.417
9 – Transfer of chemicals into small containers (dedicated filling line)	No	4 to 8	No	5 to 25	0.15	0.417
10 – Roller application or brushing	No	4 to 8	No	5 to 25	0.125	0.347
11 – Non industrial spraying based on TNsG (European Commission 2002)	No	Up to 6	95%	10	0.325	0.903
13 – Treatment of articles by dipping and pouring	No	4 to 8	No	5 to 25	0.15	0.417
15 – Use of laboratory reagents in	No	4 to 8	No	5 to 25	0.15	0.417



	<p>small scale laboratories</p> <p>19 – Hand-mixing with intimate contact (only PPE available): modelled with ConsExpo</p>	No	8	No	10	0.0002	0.001																																				
Workers (dermal)	Dermal exposure was not assessed, as no risks are anticipated with dermal exposure.																																										
Indirect exposure via the environment	No indirect exposure of humans to kieselguhr soda ash flux-calcined is anticipated.																																										
Consumer exposure (inhalation)	<p>Consumer exposure to kieselguhr soda ash flux-calcined resulting from the use of mixtures was described as long-term exposure in the case of use of paints and cleaning products and as short-term exposure in the case of spray painting and use of filtration materials. The long-term and acute airborne concentrations of the substance for the different uses are given in the table below. The RCRs for all consumer uses resulting in long-term exposure to the substance are well below 1 indicating that potential health risks for consumers are adequately controlled. Spray painting may result in relatively high acute exposure to kieselguhr soda ash flux-calcined and should be performed only in well-ventilated areas. It is recommended that particles of the substance used in spray paints available to consumers exhibit diameters greater than 0.015 mm. As particles with larger diameters generally are not inhaled this helps to avoid elevated consumer exposure to particles of kieselguhr soda ash flux-calcined during spray painting. The use of articles made from rubbers or plastics containing the substance is considered safe as no release of kieselguhr soda ash flux-calcined is anticipated. It is concluded that the potential health risks for consumers are adequately for the uses of the substance described in the present exposure scenario.</p>																																										
<i>DNEL: Consumer, long-term, systemic, inhalation 0.08: mg/m<sup>3</sup></i>	<table border="1"> <thead> <tr> <th>Consumer use</th> <th>Mean inhalation concentration (long-term) in mg/m<sup>3</sup></th> <th>Mean inhalation concentration (acute) in mg/m<sup>3</sup></th> <th>RCR</th> </tr> </thead> <tbody> <tr> <td>Use of high-solid paints</td> <td>0.000122</td> <td></td> <td>0.0015</td> </tr> <tr> <td>Use of water-based paints</td> <td>0.000186</td> <td></td> <td>0.0023</td> </tr> <tr> <td>Use of solvent-based paints</td> <td>0.000864</td> <td></td> <td>0.011</td> </tr> <tr> <td>Use of water-based wall paints</td> <td>0.00044</td> <td></td> <td>0.0055</td> </tr> <tr> <td>Spray painting (trigger cans)</td> <td>Not applicable</td> <td>37.5</td> <td>Not applicable</td> </tr> <tr> <td>Spray painting (pneumatic sprayer)</td> <td>Not applicable</td> <td>0.676</td> <td>Not applicable</td> </tr> <tr> <td>Filtration material</td> <td>Not applicable</td> <td>0.14</td> <td>Not applicable</td> </tr> <tr> <td>Cleaning products</td> <td>0.00002</td> <td></td> <td>0.00025</td> </tr> </tbody> </table>							Consumer use	Mean inhalation concentration (long-term) in mg/m <sup>3</sup>	Mean inhalation concentration (acute) in mg/m <sup>3</sup>	RCR	Use of high-solid paints	0.000122		0.0015	Use of water-based paints	0.000186		0.0023	Use of solvent-based paints	0.000864		0.011	Use of water-based wall paints	0.00044		0.0055	Spray painting (trigger cans)	Not applicable	37.5	Not applicable	Spray painting (pneumatic sprayer)	Not applicable	0.676	Not applicable	Filtration material	Not applicable	0.14	Not applicable	Cleaning products	0.00002		0.00025
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<b>5.2. Environmental exposure (qualitative assessment)</b>																																											
Waste water treatment plants (WWTP)	<p>Kieselguhr soda ash flux-calcined used for the filtering of drinking and swimming pool water and kieselguhr soda ash flux-calcined present in surface cleaners may be released to the sewer and subsequently pass a municipal sewage treatment plant (STP). As the tonnages of kieselguhr soda ash flux-calcined for these uses are not known, a worst-case is considered in the present assessment in that 10% of the total tonnage placed on the EU market ends up in municipal STPs due to industrial, professional and private use of mixtures containing the substance and not covered by other exposure scenarios. The total EU tonnage is 120,000 tonnes per year resulting in 12,000 tonnes of kieselguhr soda ash flux-calcined released to municipal STPs in the present scenario. This amount is evenly distributed over the EU as dispersive use of mixtures containing the substance can be assumed. The EU has approximately 500 millions inhabitants. The average</p>																																										

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	<p>volume of wastewater per inhabitant equivalent is 200 L per day (EUSES default). The concentration in a municipal STP can then be calculated as:</p> $C_{STP} = \frac{AMOUNT_{STP}}{DAYS \cdot INHAB \cdot WASTEW_{inhab}}, \text{ where}$ <p><i>AMOUNT<sub>STP</sub></i> : amount of kieselguhr soda ash flux-calcined released to municipal STPs in the EU per year (1.2E13 mg/year),  <i>DAYS</i> : number of release days (365 days/year),  <i>INHAB</i> : number of inhabitants in EU (500 millions inhabitants),  <i>WASTEW<sub>inhab</sub></i> : wastewater per inhabitant (200 L/d) ,  <i>C<sub>STP</sub></i> : concentration of kieselguhr soda ash flux-calcined in municipal STP (mg/L).</p> <p>The predicted concentration of kieselguhr soda ash flux-calcined in municipal sewage treatment plants is then:</p> $C_{STP} = \frac{1.2E13}{365 \cdot 500000000 \cdot 200} = 0.329 \frac{mg}{L}.$
Aquatic pelagic compartment	A dilution factor of 10 is taken into account at the point of mixing of the waste water with surface water, leading to a surface water concentration of 0.033 mg/L. For coastal areas a dilution factor of 100 is taken into account, leading to a concentration of 0.00033 mg/L in marine waters
Sediments	Kieselguhr is a naturally occurring sedimentary rock consisting of the shells of diatoms which is formed in water bodies and is therefore considered a natural part of the ecosystem. Therefore, no risk is anticipated with kieselguhr soda ash flux-calcined in sediments and no exposure assessment for sediment is carried out
Soil and groundwater	If paints containing soda ash flux-calcined are used outdoors small amounts of kieselguhr soda ash flux-calcined may leach to the soil. Further, kieselguhr soda ash flux-calcined may be released to soil via atmospheric deposition and via sewage sludge brought to agricultural fields and grassland. Kieselguhr is a naturally occurring sedimentary rock which is essentially a mineral fraction of soil already. Only the accidental release of a significant quantity kieselguhr soda ash flux-calcined is expected to alter the physical and chemical characteristics of a soil. As leaching from paints and atmospheric deposition to soil is regarded as minor and the deposition of sewage sludge to fields takes place under controlled conditions no risk is anticipated with the release of kieselguhr soda ash flux-calcined to soil from the use described in this scenario and thus, no further assessment of the exposure concentrations in soil is undertaken
Atmospheric compartment	Emissions of kieselguhr soda ash flux-calcined into the atmosphere are low during the use of mixtures containing the substances by industrial workers, professionals or consumers. The atmospheric concentrations of the substance are expected to be low. No further assessment of the exposure concentrations in the atmosphere is undertaken.
Secondary poisoning	It is expected that emissions of the substance resulting from the industrial, professional or private use of the substance or mixtures containing the substance will not significantly increase the naturally occurring concentrations of kieselguhr or other compounds in the environment. The potential of kieselguhr soda ash flux-calcined for bioaccumulation is low. The substance has a low solubility in water and thus is essentially unavailable to organisms. Therefore, it is not necessary to assess secondary poisoning via the food chain