UNID
(주)유니드

Extended SAFETY DATA SHEET

According to Regulation(EC) No 1907/2006(REACH)

1. Identification of the substance/mixture and of the company

1.1 Product identifier:
Substance name: Potassium carbonate
EC No.: 209-529-3
REACH Registration No.: 01-2119532646-36-0003
CAS No.: 584-08-7

1.2. Relevant identified uses of the substance or mixture and uses advised against
-Industrial and professional uses
Industrial uses cover among others the manufacture of potassium carbonate as such and the use in preparations at industrial sites, manufacture of bulk, large scale chemicals (including petroleum products), fine chemicals as well as formulation (mixing) of preparations containing or involving the use of potassium carbonate.
-Consumer uses
Consumer uses cover the use of potassium carbonate in anti-freeze and de-icing products, disinfectants, coatings and paints, thinners, paint removers, fertilizers, ink and toners, plant protection products, photo-chemicals, washing and cleaning products (including solvent based products) as well as stone-, plaster-, cement-, glass-, ceramic-, metal-, paper-, rubber-, wood- and plastic articles.

1.2.2 Uses advised against
: There are no uses advised against.

1.3. Details of the supplier of the SDS
Supplier(Manufacturer)
Unid Co., Ltd. Incheon Factory
587-84 Hagik 1-Dong, Nam-gu, Incheon, South Korea
Tel : + 82-32-830-7777, Fax :+82-32-832-4491
E-mail : kjhyun@unid.co.kr
National contact : K.J Hyun

1.4. Emergency telephone number
Opening hours: 09:00 ~ 17:00
Manufacturer's European Contact :
OCI UNID Europe B.V
Rivium Quadrant 81. 2090 LC Capelle a/d Ijssel. Netherlands
Tel : +31 10 360 1012 Fax : +31 10 202 5466
E-mail :sujlee@unid.co.kr
Contact :S.J Lee

2. Hazards identification

2.1 Classification of the substance

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP/GHS]
Skin Irritation; category 2
Eye Irritation; category 2
STOT Single Exposure; category 3
H315, H319

2.1.2 Classification according to Directive 67/548/EEC
Xi – irritant
R36, R37, R38
S25, S26, S36/37/39

2.1.3 Additional information
- For full text of R-phrases and Hazard- and EU Hazard-statements: see section 16

2.2. Label elements
Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS]

Hazard pictograms

GHS07

Signal word:
Warning

Hazard statements:
H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation

Precautionary statements:
P261 Avoid breathing dust/ fume/ mist / vapours / spray
P264 Wash hands thoroughly with soap and water after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing.
P362 Take off contaminated clothing and wash before reuse)
P403+P233 Store in a well-ventilated place. Keep container tightly closed.)

Supplemental Hazard information (EU): N/A

2.3 Other hazards
KOH is not considered a PBT or a vPvB substance.

3. Composition/information on ingredients

Substances

Product identifier type in accordance with Article18(2) of Regulation(EC) No 1272/2008	Identifier number	Identification name	Weight(%) Content (or range)	EC Number
CAS number	584-08-7	potassium carbonate	>= 99.5 %	209-529-3
CAS number	497-19-8	sodium carbonate	<= 0.3 %	207-838-8
CAS number	1310-58-3	potassium hydroxide	<= 0.2 %	215-181-3

4. First aid measures

4.1. Description of first aid measures

- general notes
Pay attention to self-protection.
Remove victims from hazardous area. Immediately remove soiled or soaked clothing and remove it to a safe distance. Keep victim warm, in a stabilized position and covered. Do not leave victims

unattended. If the casualty is unconscious: Place the victim in the recovery position.

- following inhalation
Inhalation is possible if aerosols, mists, dusts, or smoke form.
Move victims into fresh air. With labored breathing: Provide with oxygen. Consult a doctor.
If the casualty is not breathing: Perform mouth-to-mouth resuscitation, notify emergency physician immediately.

- following skin contact
Wash off affected area immediately with plenty of water for at least 15 minutes.
With liposoluble substances, products, or preparations, continue decontamination with polyethylene glycol 400 after initial rinsing with water and then wash with water and soap. If symptoms persist, consult a physician for treatment.

- following eye contact
With eye held open, thoroughly rinse immediately with plenty of water for at least 10 minutes.
Consult an ophthalmologist immediately if the symptoms persist. When dealing with caustic substances, notify emergency physician immediately (key words: burns in eye).

- following ingestion
Rinse out mouth. Immediately give large quantities of water to drink. Consult a physician immediately.
When dealing with caustic substances, notify emergency physician immediately.

4.2. Most important symptoms and effects, both acute and delayed: N/A

4.3. Indication of any immediate medical attention and special treatment needed
In case of substances with high water solubility, inhalation of vapors, aerosols, mists, and smoke from caustic substances, products, and preparations, as well as caustic gases, results in irritations up to formation of necrosis in the upper respiratory tract. The initial focus is on the local action: signs of irritation of the respiratory tract such as coughing, burning behind the sternum, tears, burning in the eyes or nose. There is a fundamental risk of acute toxic pulmonary edema!
In case of substances with low water solubility, only slight local irritations may appear at first, but after several hours of latency without symptoms, may develop into increasingly labored breathing and cyanosis as a result of a delayed pulmonary edema. There is a danger of underestimating the severity of the intoxication!

5. Fire-fighting measures

5.1 Extinguishing media:
Suitable extinguishing media:
- The product is not combustible.,
  In case of fire in the surroundings: Water spray, foam, CO2, dry powder.
Unsuitable extinguishing media:
- high volume water jet

5.2 Special hazards arising from the substance or mixture
- The product itself does not burn.

5.3 Advice for fire-fighters
- Water used to extinguish fire should not enter drainage systems, soil, or stretches of water Ensure there are sufficient retaining facilities for water used to extinguish fire. Contaminated fire-extinguishing water must be disposed of in accordance with the regulations issued by the appropriate local authorities. Fire residues should be disposed of in accordance with the regulations.
-Special protective equipment for fire-fighters; Wear suitable protective clothing.

5.4 Additional information: N/A

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
- Wear personal protective equipment.

6.2 Environmental precautions:
- Prevent product from entering drains.
- Do not allow entrance in sewage water, soil or stretches of water.

6.3 Methods and material for containment and cleaning up
- Use mechanical handling equipment.
- After cleaning, flush away traces with water.

6.4 Reference to other sections
N/A

7. Handling and storage

7.1 Precautions for safe handling
-Precautions for safe handling
-Avoid dust formation.
-Wear personal protective equipment.
-Advice on protection against fire and explosion; No special precautions required.

7.2 Conditions for safe storage, including any incompatibilities
-Conditions for safe storage, including any incompatibilities
-Keep container tightly closed in a dry and well-ventilated place.
-Unsuitable materials copper, brass, light metals
-German storage class: 13 - Non Combustible Solids

7.3 Specific end use(s):
Exposure scenario for the mixture is attached.

8. Exposure controls/personal protection

8.1 Control parameters

8.1.1 Occupational Exposure limit values(OEL)
*Data contained in the Safety use

Control parameters
- 10 mg/ m³ MAK(TRGS 900)
type of exposition Inhalable fraction.
Remarks General dust limiting value(s):
-3 mg/ m³ MAK(TRGS 900)
type of exposition as alveolar accessible part
Remarks General dust limiting value(s):

*Data contained in the CSR

the OEL of potassium carbonate should be higher than 5 mg/m3. Therefore, a correction factor can be applied. Considering the specific concentration limits set for the irritating nature of each substance a correc-tion factor of 2 seems to be appropriate. As a conservative estimate it is assumed that the estimated OEL of potassium carbonate is only a factor 2 higher than the OEL of calcium hydroxide. This results in an OEL of 10 mg/m3 for potassium carbonate (inhalable fraction). A value of 10 mg/m3 is similar to the general dust limit of inert dust (inhalable fraction).

8.1.2 Biological limit value:
N/A

8.1.3 Exposure limits at intended use:

N/A

8.1.4 DNEL/PNEC-values
DNEL for long-term inhalation, workers is 10.0 mg/m³
DNEL for long-term inhalation, consumers is 10.0 mg/m³

8.1.5 Risk management measures according to used control banding approach: N/A

8.2 Exposure controls

8.2.1 Appropriate engineering controls:
N/A

8.2.2 Personal protection equipment:
8.2.2.1 Eye and face protection:
- safety glasses

8.2.2.2 Skin protection:
Hand protection: suitable protective gloves
-Glove material butyl-rubber, PVC, Polychloroprene with natural-latex liner.
Material thickness 0,5 mm
Break through time > 480 min
Method DIN EN 374
-Glove material nitrile rubber (Camatril, Tricotril, Dermatril), Fluorinated rubber (Vitoject)
Material thickness 0,35 - 0,4 mm
Break through time > 480 min
Method Source: KCL GmbH
Body protection: N/A
Other protection:
Hygiene measures:
-Wash off immediately in the event of contact with the skin
(rinsing agent: glycol polyethylene 400), rinse off afterwards with copious amounts of water.
-No eating, drinking, smoking, or snuffing tobacco at work.
-Wash face and/or hands before break and end of work.
-Take off clothing and shoes contaminated with product. Clean before reuse.
-Avoid dust formation.

8.2.2.3 Respiratory protection:
- In case of dusts/vapours/aerosols being formed or if the limit values like TLV are exceeded: use respiratory equipment with suitable filter or wear a self contained respiratory apparatus

8.2.3 Environmental exposure controls: N/A

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Property	Results
Appearance at 20°C and 101.3 hPa	Physical state: Solid(crystalline; powder) Colour: white
odour	odourless
odour threshold	N/A
pH	N/A
Melting / freezing point	Melting point: 891 °C
Boiling point	Boiling point: not measurable due to decomposition
Flash point	N/A
Evaporation rate	N/A

Property	Results
Flammability	N/A
Upper/lower flammability or explosive limits	N/A
Vapour pressure	N/A
Vapour density	N/A
Relative density	2.43 at 19°C
Water solubility	900-1105g/L at 20°C
Partition coefficient: n-octanol-water	N/A
Auto-ignition temperature	N/A
Decomposition temperature	N/A
Viscosity	N/A
Explosive properties	N/A
Granulometry	Potassium carbonate: Mean particle sizes D95: >2000µm , 95% w/w; D50: >750µm , 60%w/w D5: >100µm.29% w/w (typical produced quality)

9.2 Other information: N/A

10. STABILITY AND REACTIVITY

10.1 Reactivity
N/A
10.2 Chemical stability
N/A
10.3 Possibility of hazardous reactions
N/A
10.4 Conditions to avoid:
N/A
10.5 Incompatible materials: acids
Further information: Exothermic reaction with acids; evolution of carbon dioxide.
10.6 Hazardous decomposition products:
N/A

11. Toxicological information:

Acute toxicity:

	Dose	Species	Method	Remark
Acute oral toxicity	LD50 2000 mg/kg bw	rat	Equivalent or Similar to OECD Guideline 401	
Acute inhalative toxicity	LC50 4.96 mg/L air	rat	US EPA Pesticide Assessment Guidelines	
Acute dermal toxicity	LD50 2000 mg/kg bw	rabbit	US EPA Pesticide Assessment Guidelines	

Irritation:
Potassium carbonate has an intrinsic irritating activity.
Skin irritation / corrosion: irritating

Eye irritation / corrosion: irritating
Respiratory tract irritation: irritating

Corrosivity:
Potassium carbonate shows indications of intrinsic irritating activity. Serious eye irritation caused by potassium carbonate is documented; however, no clear proof that it is not reversible after 21 days is given due to study design. Furthermore, data from accidental exposure to humans indicate a slight irritation potential to skin and a serious irritation potential to the eyes. In animal studies no irritation potential for intact skin has been documented. The irritating activity of potassium carbonate is solely based on alkalinity. In mixtures, the acid reserve of the additional compounds may compensate the alkalinity of potassium carbonate and herewith its irritancy.
These considerations are supported by read-across to the related substance sodium carbonate (soda ash) for which a Hera Risk Assessment, a SIDS dossier and an official classification is available. In these documents the irritating nature of sodium carbonate is described.

Sensitisation
Skin

	Method	Results	Remarks
Non-human information	guinea pig (Hartley) Buehler test Induction: epicutaneous, occlusive Challenge: epicutaneous, occlusive US EPA Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals, November 1984, Acute Exposure, Guinea Pig Sensitization (Buehler)	not sensitising No. with positive reactions: 1st reading: 0 out of 10 (test group); 24 h after chall.; dose: 95 % 2nd reading: 0 out of 10 (test group); 48 h after chall.; dose: 95 % 1st reading: 0 out of 5 (negative control); 24 h after chall.; dose: 95 % 2nd reading: 0 out of 5 (negative control); 48 h after chall.; dose: 95 %	2 (reliable with restrictions) key study experimental result Test material: CAS 584-08-7
Human information	Study type: case report Type of population: occupational Subjects: Patch tests were carried out with the European standard series and variuos diluted working products: amongst others: potassium carbonate 1%.	No response to potassium carbonate.	4 (not assignable) supporting study Test material: CAS 584-08-7

Respiratory system: No data available.

Repeated dose toxicity:
Non-human information

	Method	Results	Remarks
oral	rat (Wistar) male/female chronic (oral: feed) 2 and 4 % in the diet (nominal in diet) Exposure: 130 weeks (30 months) (daily) Non-guideline 30-month-study to examine the effects of died-induced acid-base disturbances.	NOAEL: 2667 mg/kg bw/day (actual dose received) (male) NOAEL: 3331 mg/kg bw/day (actual dose received) (female)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) Test material (EC name): potassium hydrogencarbonate
	rat (Wistar) male/female chronic (oral: feed) 2 and 4 % in the diet (nominal in diet) Exposure: 78 weeks (18 months) (daily) Non-guideline 18-month-study to examine the effects of died-induced acid-base disturbances.	NOAEL: 2861 mg/kg bw/day (actual dose received) (male) NOAEL: 3566 mg/kg bw/day (actual dose received) (female)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (EC name): potassium hydrogencarbonate

	Method	Results	Remarks
	rat (Wistar) male/female subchronic (oral: feed) 2 and 4 % in the diet (nominal in diet) Exposure: 13 weeks (daily) Non-guideline 13-week-study to examine the effects of died-induced acid-base disturbances.	NOAEL: 4326 mg/kg bw/day (actual dose received) (male) NOAEL: 4879 mg/kg bw/day (actual dose received) (female) (Highest dose tested (4% in diet); no adverse effects relevant to humans observed; only adaptive effects on very high ion ingestion seen.)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (EC name): potassium hydrogencarbonate
	rat (Wistar) male/female subacute (oral: feed) 2 and 4 % in diet (nominal in diet) Exposure: 4 weeks (daily) Non-guideline 4-week-study to examine the effects of died-induced acid-base disturbances.	NOAEL: 6054 mg/kg bw/day (actual dose received) (male) NOAEL: 6137 mg/kg bw/day (actual dose received) (female) (Highest dose tested (4 % in diet); no adverse effects relevant to humans observed; only adaptive effects on very high ion ingestion seen.)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (EC name): potassium hydrogencarbonate
inhalation	rat (Sprague-Dawley) male/female subacute (inhalation) (whole body) 0.1, 0.2 and 0.4 mg used scrubbing solution/L (nominal conc.) 0.11, 0.16 and 0.41 mg used scrubbing solution/L (analytical conc.) Vehicle: The aerosol concentration was reduced to the target concentrations by dilution with the chamber ventilation air flow. Exposure: 21 days (daily, 6 hours per day) equivalent or similar to OECD Guideline 412 (Repeated Dose Inhalation Toxicity: 28/14-Day) equivalent or similar to OECD Guideline 424 (Neurotoxicity Study in Rodents)	NOAEC (local): 0.2 mg/L air (analytical) NOAEC (local): 0.062 mg/L air NOEC (systemic): 0.4 mg/L air (analytical) NOEC (systemic): 0.123 mg/L air (male/female) NOEC (neurotoxicity): 0.4 mg/L air (analytical) NOEC (neurotoxicity): 0.123 mg/L air LOEC (local): 0.1 mg/L air (analytical) LOEC (local): 0.031 mg/L air (male/female)	2 (reliable with restrictions) supporting study experimental result Test material: used scrubbing solution Cartacarb, main active ingredient 30.8 % potassium carbonate
dermal	N/A		No data available

Human information: No data available.

Mutagenicity:

In vitro data

Method	Results	Remarks
bacterial reverse mutation assay (e.g. Ames test) (gene mutation) Doses: up to and including 10 mg/plate, 6 concentrations were tested equivalent or similar to OECD Guideline 471 (Bacterial Reverse Mutation Assay) (1983)	Evaluation of results: negative Test results: negative (strain/cell type: Salmonella typhimurium TA 92, TA 94, TA 98, TA 100, TA 1535, TA 1537); met. act.: with and without; cytotoxicity: not reported	2 (reliable with restrictions) key study experimental result Test material: CAS 584-08-7
bacterial reverse mutation assay (e.g. Ames test) (gene mutation) Doses: 0, 100, 500, 1000, 5000, 10000 µg/plate equivalent or similar to OECD Guideline 471 (Bacterial Reverse Mutation Assay)	Evaluation of results: negative Test results: negative for S. typhimurium, other: Salmonella typhimurium TA97, TA102 (all strains/cell types tested);	2 (reliable with restrictions) key study experimental result Test material: CAS 584-08-7

Method	Results	Remarks
	met. act.: with and without; cytotoxicity: not reported	
mammalian cell gene mutation assay (gene mutation) mouse lymphoma L5178Y cells (met. act.: with and without) Doses: Trial 1 to 3 without metabolic activation and Trial 2 and 3 with metabolic activation tested up to (and incl.) 5000 µg/mL Trail 1with metabolic activation tested incl. 4000 µg/mL. equivalent or similar to OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)	Evaluation of results: negative without metabolic activation negative with metabolic activation Test results: negative for mouse lymphoma L5178Y cells (all strains/cell types tested); met. act.: without; cytotoxicity: yes positive (probably due to osmolality effects) for mouse lymphoma L5178Y cells(all strains/cell types tested); met. act.: with; cytotoxicity: yes	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) Test material (EC name): potassium chloride
mammalian cell gene mutation assay (gene mutation) mouse lymphoma L5178Y cells (met. act.: with and without) Doses: Trial 1 and 2 with and without metabolic activation tested up to (and incl.) 5000 µg/mL Trial 3: Without metabolic activation: 4000, 5000, 7000, 8000, 9000 µg/mL With metabolic activation (induced): 2000, 4000, 5000, 6000, 7000, 8000 µg/mL equivalent or similar to OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)	Evaluation of results: negative without metabolic activation negative with metabolic activation Test results: negative for mouse lymphoma L5178Y cells(all strains/cell types tested); met. act.: without; cytotoxicity: yes ambiguous (weak mutagenic effect, probably due to osmolality effects) for mouse lymphoma L5178Y cells(all strains/cell types tested); met. act.: with; cytotoxicity: yes	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) Test material (EC name): potassium chloride
in vitro mammalian chromosome aberration test (chromosome aberration) Chinese hamster fibroblast cell line CHL (met. act.: without) Doses: 3 concentrations (not further specidied) including the highest non-cytotoxic concentration of 1000 µg/mL were tested equivalent or similar to OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)	Evaluation of results: negative without metabolic activation (not tested with metabolic activation) Test results: negative for Chinese hamster fibroblast cell line CHL(strain/cell type: Chinese hamster fibroblast cell line CHL); met. act.: without; cytotoxicity: Highest non-cytotoxic concentration 1000 µg/mL	2 (reliable with restrictions) key study experimental result Test material: CAS 584-08-7

In vivo data: N/A
Information requirement: Genetic toxicity in vivo testing
Reason: other justification
Justification: There was no evidence for an intrinsic mutagenic or genotoxic activity of potassium carbonate relevant to humans. The evaluated studies cover the full set of in vitro tests required by REACH Regulation Annexes VII and VIII. Substances that are negative in the full set of in vitro tests specified in REACH Regulation Annexes VII and VIII are considered to be non-genotoxic. According to REACH Regulation Column 2 of Annex VIII 8.4 additional in vivo testing is not required.

Human information: No data available.

Carcinogenicity:
Non-human information
oral

Method	Results	Remarks
rat (Wistar) male/female oral: feed 2 and 4 % in the diet (nominal in	NOAEL (carcinogenicity): 2667 mg/kg bw/day (actual dose received) (male)	2 (reliable with restrictions) supporting study read-across from supporting

Method	Results	Remarks
diet) Non-guideline 30-month-study to examine the effects of died-induced acid-base disturbances. Diets were supplemented with high amounts of potassium hydrogencarbonate (2% or 4%, base-forming diets).	NOAEL (carcinogenicity): 3331 mg/kg bw/day (actual dose received) (female)	substance (structural analogue or surrogate) Test material (EC name): potassium hydrogencarbonate
rat (Wistar) male/female oral: feed 2 and 4 % in the diet (nominal in diet) Non-guideline 18-month-study to examine the effects of died-induced acid-base disturbances. Diets were supplemented with high amounts of potassium hydrogencarbonate (2% or 4%, base-forming diets).	NOAEL (carcinogenicity): 2861 mg/kg bw/day (actual dose received) (male) NOAEL (carcinogenicity): 3566 mg/kg bw/day (actual dose received) (female) (Highest dose tested (4% in diet); there were no treatment-related changes in any specific tumour type among the groups; potassium hydrogencarbonate did neither affect type, incidence and multiplicity of tumours, nor time of tumour appearance and the ratio benign-malignant tumours relevant to humans.)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (EC name): potassium hydrogencarbonate (See endpoint summary for justification of read-across)

Inhalation: No data available.
Dermal: No data available.
other routes: No reliable data available.

Human information: Please refer to discussion.

Toxicity for reproduction:
Effects on fertility
Non-human information: N/A
Reason: study scientifically unjustified
Justification: In accordance with section 1of REACH Annex XI, the study does not appear scientifically necessary. Developmental toxicity / teratogenicity studies on potassium carbonate are available. In these studies there were no indications on any reproductive effects. In repeated dose toxicity studies on potassium carbonate and potassium hydrogencarbonate, the reproductive organs were free of treatment related effects. Further on, based on chemistry considerations of the structure of potassium carbonate, no reproductive toxicity is expected. Undissociated potassium carbonate is not expected to be systemically available in the body under normal handling and use conditions and for this reason it can be stated that the substance will not reach the foetus nor reach male and female reproductive organs. The abiotic dissociation of potassium carbonate with tissue water results in the formation of potassium and carbonate ions. Potassium and carbonate ions are naturally occurring, effectively processed and regulated essential compounds in the body. K+ or CO32- resulting from the ionisation (dissociation) of K2CO3 will not influence the natural K+ or CO32- level in the body due to the natural regulation mechanisms. For this reason it is very unlikely that potassium carbonate has an intrinsic reproductive toxicity. Missing intrinsic toxic properties of potassium carbonate is generally taken for granted, which is proved by its long-standing safe use in food and pharmaceuticals and its GRAS (generally recognized as safe) status in the USA. In accordance with the European Parliament and Council Directive No 95/2/EC potassium carbonate may be added to almost all foodstuffs - including foodstuffs for infants and children - following the quantum satis principle. This means that no maximum level is specified. However, potassium carbonate shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose. Also according to JECFA (Joint FAO/WHO Expert Committee on Food Additives) Potassium carbonate (501(i)) has the ADI evaluation "not limited" and may therefore be used in food stuffs with no limitations other than current good manufacturing practice (Codex Alimentarius specification INS

number 501 (i), http: //www. fao. org/ag/agn/jecfa-additives/specs/Monograph1/Additive-333. pdf) and FAO/WHO Codex Alimentarius GSFA (General Standard for Food Additives) online, http: //www. codexalimentarius. net/gsfaonli-ne/additives/details. html?id=199)

Human information: No data available.

Developmental toxicity
Non-human information

Method	Results	Remarks
rat (Wistar) oral: gavage 1.8, 8.4, 38.8 or 180.0 mg/kg bw per day (actual ingested) Exposure: day 6 to 15 of gestation (once daily) equivalent or similar to OECD Guideline 414 (Prenatal Developmental Toxicity Study)	NOEL (maternal toxicity): 180 mg/kg bw/day (highest dose tested; no effects) NOEL (teratogenicity): 180 mg/kg bw/day (highest dose tested; no effects) NOEL (fetotoxicity): 180 mg/kg bw/day (highest dose tested; no effects)	2 (reliable with restrictions) key study experimental result Test material: CAS 584-08-7
mouse (CD-1) oral: gavage 2.9, 13.5, 62.5 or 290.0 mg/kg bw Exposure: day 6 to 15 of gestation (once daily) equivalent or similar to OECD Guideline 414 (Prenatal Developmental Toxicity Study)	NOEL (maternal toxicity): 290 mg/kg bw/day (highest dose tested; no effects) NOEL (teratogenicity): 290 mg/kg bw/day (highest dose tested; no effects) NOEL (fetotoxicity): 290 mg/kg bw/day (highest dose tested; no effects)	2 (reliable with restrictions) key study experimental result Test material: CAS 584-08-7
rat (Sprague-Dawley) inhalation (whole body) 0.05, 0.1, 0.2 and 0.3 mg used scrubbing solution/L (nominal conc.) 0.057, 0.93, 0.206 and 0.329 mg/L (mean gravimetric concentration) 0.54, 0.086, 0.189 and 0.313 mg/L (analytical conc. (based on potassium measurement)) Exposure: day 6 to 19 of gestation (daily, 6 hours per day) EPA OPPTS 870.3700 (Prenatal Developmental Toxicity Study) EPA OPP 83-3 (Prenatal Developmental Toxicity Study) U.S. Environmental Protection Agency (1986) Guidelines for Health Assessment of Suspect Developmental Toxicants. Fed. Reg. 51 (185):34028-34034	NOAEC (maternal toxicity): 0.2 mg/L air (analytical) (one animal died in the 0.3 mg/L dose group, in all dose groups localized effects in the respiratory tract (rales) likely due to the irritating properties of the alkaline solution, based on product) NOAEC (maternal toxicity): 0.062 mg/L air (recalculated, based on amount of potassium carbonate in product) NOEC (teratogenicity): 0.3 mg/L air (analytical) (highest tested concentration, no effects, based on product) NOEC (teratogenicity): 0.092 mg/L air (recalculated, based on amount of potassium carbonate in product) NOEC (embryotoxicity): 0.2 mg/L air (analytical) (skeletal variations in form of delayed mineralization of sternal elements in two litters attributed to the two most severely affected dams, based on product) NOEC (embryotoxicity): 0.062 mg/L air (recalculated, based on amount of potassium carbonate in product)	2 (reliable with restrictions) supporting study experimental result Test material: used scrubbing solution Cartacarb, main active ingredient 30.8 % potassium carbonate

Human information: No data available.

Other effects:

Neurotoxicity
There are no indications on an intrinsic neurotoxic activity of potassium carbonate. FOB, locomotor activities, brain weight and size, neurohistopathology were assessed in the course of a 21-day repeated dose toxicity study equivalent or similar to OECD Guideline 412 (Repeated Dose Inhalation Toxicity: 28/14-Day) and equivalent or similar to OECD Guideline 424 (Neurotoxicity Study in Rodents) on a potassium carbonate based scrubbing solution (Bui Q Q et al., 1998). For further details please refer to Chapter 5.6.1.2.
Immunotoxicity: No data available.
Specific investigations: other studies
No relevant data available.
Human information: No data available.

12. Ecological information

12.1 Toxicity:

12.1.1 Aquatic compartment(including sediment)

Short-term toxicity to fish

Method	Results	Remarks
Oncorhynchus mykiss freshwater flow-through FIFRA Guideline 72-1 (national standard, US, comparable to international guidelines)	LC50 (96 h): 68 mg/L act. ingr. (meas. (not specified))	2 (reliable with restrictions) key study experimental result **Test material CAS 584-08-7**

Long-term toxicity to fish: N/A
Reason: other justification
Justification: In accordance with REACH Annex IX, 9.1.6, column 2, long-term toxicity testing on fish does not need to be conducted. A test for long-term toxicity on fish is only required, if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment. The abiotic dissociation of potassium carbonate in water results in the formation of potassium and carbonate ions. Potassium and carbonate are essential for almost all living organisms including fresh- and saltwater fish and natural components in their habitats.

Aquatic invertebrates
Short-term toxicity to aquatic invertebrates

Method	Results	Remarks
Daphnia pulex freshwater static FIFRA Guideline 72-1 (national standard, US, comparable to international guidelines)	EC50 (48 h): 200 mg/L act. ingr. (meas. (not specified)) based on: mobility	2 (reliable with restrictions) key study experimental result **Test material CAS 584-08-7**
Daphnia magna freshwater static FIFRA Guideline 72-1 (national standard, US, comparable to international guidelines)	EC50 (48 h): 430 mg/L act. ingr. (meas. (not specified)) based on: mobility	2 (reliable with restrictions) supporting study experimental result **Test material CAS 584-08-7**

Long-term toxicity to aquatic invertebrates: N/A
Reason: other justification
Justification: In accordance with REACH Annex IX, 9.1.5 column 2, long-term toxicity testing on aquatic invertebrates does not need to be conducted. A test for long-term toxicity on aquatic invertebrates is only required, if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s)

depends on the results of the chemical safety assessment. The abiotic dissociation of potassium carbonate in water results in the formation of potassium and carbonate ions. Potassium and carbonate are essential for almost all living organisms including fresh- and saltwater fish and natural components in their habitats. This is in line with the fact that standard guidelines, e. g. OECD 201, aquatic test media should be enriched with potassium (e. g. as KH_2PO_4) and carbonate (e. g. as $NaHCO_3$) to ensure appropriate living conditions. Therefore, potassium carbonate is not expected to have an intrinsic toxic activity to aquatic organisms.

Algae and aquatic plants: N/A
Information requirement: Growth inhibition study with algae / cyanobacteria
Reason: other justification
Justification: In accordance with REACH Annex VII, 9.1.2, column 2, the study on algae growth inhibition does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur. The abiotic dissociation of potassium carbonate in water results in the formation of potassium and carbonate ions. Potassium and carbonate are essential for almost all living organisms including aquatic plants and algae and natural components in their habitats. This is in line with the fact that standard guidelines, e. g. OECD 201, aquatic test media should be enriched with potassium (e. g. as KH_2PO_4) and carbonate (e. g. as $NaHCO_3$) to ensure appropriate living conditions. Therefore, potassium carbonate is not expected to have an intrinsic toxic activity to aquatic organisms

Sediment organisms: N/A
Reason: other justification
Justification: In accordance with REACH Annex X, 9.5.1. long-term toxicity testing on sediment dwelling organisms is only required, if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on terrestric organisms. The abiotic dissociation of potassium water results in the formation of potassium and carbonate ions. Potassium as well as carbonate are ubiquitously present in the environment, occurring naturally in minerals, soils and sediments, natural waters (oceans, lakes, rivers), biota and human beings. Potassium and carbonate are essential for almost all living organisms including sediment organisms and natural components in their habitats. Therefore, potassium carbonate is not expected to have an intrinsic toxic activity to sediment organisms.

12.1.2 Terrestrial compartment
Toxicity to soil macro-organisms: N/A
Information requirement: Toxicity to soil macro-organisms except arthropods
& Toxicity to terrestrial arthropods
Reason: other justification
Justification: In accordance with REACH Annex IX, 9.4.1 and Annex X, 9.4.4. short and long-term toxicity testing on terrestrial invertebrates is only required, if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on terrestric organisms. Potassium and carbonate ions are essential for almost all living organisms including terrestrial invertebrates and natural components in their habitats. The dissociation of potassium carbonate in water soil pore water results in the formation of potassium and carbonate ions. Potassium as well as carbonate is ubiquitously present in the environment, occurring naturally in minerals, soils and sediments, natural waters (oceans, lakes, rivers), biota and human beings and also in sewage. Relevant sources for their occurrence in soil are decay of biotic material, animal and human excreta and abrasion of pedospheric and lithogenic material. Therefore, potassium carbonate is not expected to have an intrinsic toxic activity to terrestrial organisms.
Test results for KCl are summarised in the following table:

Method	Results	Remarks
Eisenia sp. (annelids) short-term toxicity (laboratory study) Substrate: Two soils were used: artificial OECD soil OECD Guideline 207 (Earthworm, Acute Toxicity Tests)	NOEC : 4238 mg KCl/kg soil dw test mat. (nominal) based on: mortality LOEC : 5869 mg KCl/kg soil dw test mat. (nominal) based on: mortality LC50 (14 d): 5595 mg KCl /kg soil dw test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material (EC name): potassium chloride, CAS**

	LC50 (7 d): 5725.1 mg KCl /kg soil dw test mat. (nominal) based on: mortality	**7447-40-7**

Toxicity to terrestrial plants: N/A
Reason: other justification
Justification: In accordance with REACH Annex IX, 9.4.3 and Annex X, 9.4.6. short and long-term toxicity testing on plants is only required, if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on terrestric organisms. The dissociation of potassium carbonate in water and soil pore water results in the formation of potassium and carbonate ions. Potassium as well as carbonate is ubiquitously present in the environment, occurring naturally in minerals, soils and sediments, natural waters (oceans, lakes, rivers), biota and human beings. Potassium and carbonate are essential for almost all living organisms including terrestrial plants and natural components in their habitats. Therefore, potassium carbonate is not expected to have an intrinsic toxic activity to terrestrial organisms.

Toxicity to soil micro-organisms: N/A
Reason: other justification
Justification: In accordance with REACH Annex IX, 9.4, column 2, the study does not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The dissociation of potassium carbonate in water and soil pore water results in the formation of potassium and carbonate ions. Potassium as well as carbonate is ubiquitously present in the environment, occurring naturally in minerals, soils and sediments, natural waters (oceans, lakes, rivers), biota and human beings and also in sewage. Relevant sources for their occurrence in soil are decay of biotic material, animal and human excreta and abrasion of pedospheric and lithogenic material. Therefore, potassium carbonate and its abiotic dissociation products are common constituents of soil and not expected to have an intrinsic toxic activity to soil microorganisms

12.1.3 Atmospheric compartment: N/A
No data are available. However potassium carbonate in not considered to be relevant for the atmospheric compartment, since high water solubility and very low vapour pressure indicate that potassium carbonate will be found predominantly in aquatic environment.

12.1.4 Microbiological activity in sewage treatment systems
Toxicity to aquatic micro-organisms: N/A
Reason: other justification
Justification: In accordance with REACH Annex VIII, 9.1.4, column 2, the study does not need to be conducted, if there are mitigating factors indicating that microbial toxicity is unlikely to occur: The abiotic dissociation of potassium in water results in the formation of potassium and carbonate ions. Depending on pH of the sewage influent waters, CO_2 is the predominant species at pH values below 6.35, while HCO_3^- is the predominant species at a pH in the range between 6.35 and 10.33 and CO_3^{2-} is the predominant species at pH values above 10.33. Thus HCO3- (pKa= 10.33) is the most important species for the buffer capacity of natural waters. Therefore the pH will remain within the environmentally expected range of 6 and 10.
Furthermore potassium as well as carbonate is ubiquitously present in the environment, occurring naturally in minerals, soils and sediments, natural waters (oceans, lakes, rivers), biota and human beings and also in sewage. Relevant sources for their occurrence in the influent of sewage treatment plants are decay of biotic material, animal and human excreta and abrasion of pedospheric and lithogenic material. Therefore, the abiotic dissociation products of potassium carbonate are common constituents of the influent of sewage treatment plants and not expected to have an intrinsic toxic activity to sludge organisms.
12.1.5 Non compartment specific effects relevant for the food chain (secondary poisoning)
Toxicity to birds: N/A
Information requirement: Toxicity to birds
Reason: other justification
Justification: According to REACH Annex X, 9.6.1, column 2, any need for testing of birds should be carefully considered taking into account the mammalian dataset that is available for potassium carbonate.

Method	Results	Remarks
Agelaius phoeniceus (Redwinged blackbird) acute oral toxicity	LD50 : 100 mg/kg bw based on: mortality	4 (not assignable) supporting study experimental result **Test material CAS 584-08-7**

Toxicity to mammals: N/A
There is no information available for toxicity to free living mammals. However, as potassium carbonate does not accumulate in living organisms, secondary poisoning through the food chain is considered of no concern for mammals.

12.2 Persistence and degradability

12.2.1 Degradation
12.2.1.1 Abiotic degradation

Hydrolysis: N/A
Reason: study technically not feasible
Justification: According to REACH Regulation Annex XI, 1.1, a study on hydrolysis of potassium carbonate is scientifically unjustified, because potassium carbonate dissolves and dissociates immediately in K+ and inorganic carbon species in aquatic ecosystems including soil and sediment pore water. CO2 is the predominant species at a pH values below 6.35, while $HCO_3^{(-)}$ is the predominant species at a pH in the range between 6.35 and 10.33 and $CO_3^{(2-)}$ is the predominant species at pH values above 10.33.

Phototransformation/photolysis
Phototransformation in air: N/A
Reason: study scientifically unjustified
Justification: According to REACH Regulation (Annex XI, 1.), the study on phototransformation in air does not need to be done if the available data are sufficient for assessment. Due to the very low vapour pressure, the occurrence of potassium carbonate in the gas phase of the atmosphere is not to be expected.

12.2.2 Biodegradation
Biodegradation in water: N/A
Biodegradation is not relevant because potassium carbonate is an inorganic substance.

Biodegradation in soil: N/A
Reason: other justification
Justification: According to the REACH Regulation (Annex VIII, 9.2., column II) the study shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. No biotic degradation testing needs to be considered as the substance is inorganic.

12.3 Bioaccumulative potential
Aquatic bioaccumulation: N/A
Reason: study scientifically unjustified
Justification: According to REACH Regulation (Annex XI, 1.), the study on bioaccumulation does not need to be conducted if the available data are sufficient for assessment. Potassium carbonate is very soluble in water. Therefore, the substance does not accumulate in lipophilic tissues of living organisms. In aquatic ecosystems potassium carbonate will rapidly dissociate to potassium cation and inorganic carbon species. These are naturally-occurring ions in the environment. In animal and plant organisms, the mass balance of carbonate and potassium will be regulated by physiological mechanisms to ensure appropriate cell concentrations for natural life processes.

Terrestrial bioaccumulation: N/A
Reason: study scientifically unjustified
Justification: According to REACH Regulation (Annex XI, 1.), the study on bioaccumulation does not

need to be conducted if the available data are sufficient for assessment. Potassium carbonate is very soluble in water. Therefore, the substance does not accumulate in lipophilic tissues of living organisms. In terrestrial ecosystems potassium carbonate will rapidly dissociate to potassium cation and inorganic carbon species in soil pore water. These are naturally-occurring ions in the environment. In animal and plant organisms, the mass balance of carbonate and potassium will be regulated by physiological mechanisms to ensure appropriate cell concentrations for natural life processes.

12.4 Mobility in soil
Environmental distribution

Adsorption/desorption: N/A
Reason: other justification
Justification: According to the REACH Regulation (Annex IX, 9.3.3. column II), the study does not need to be conducted if due to the physico-chemical properties a low soil sorption potential is to be expected. Due to the ionic character and the high water solubility of potassium carbonate, no sorption onto soil and sediment organic matter occurs.

Volatilisation: N/A
Reason: study scientifically unjustified
Justification: According to REACH Regulation (Annex XI, 1.), the study on Henry's Law constant does not need to be conducted if the available data are sufficient for assessment. Due to the ionic character, potassium carbonate has a very low vapour pressure and very high water solubility. Therefore, a very low Henry's Law constant can be assumed.

Distribution modeling: N/A
Reason: study scientifically unjustified
Justification: According to REACH Regulation (Annex XI, 1.), the study on distribution modelling does not need to be conducted if the available data are sufficient for assessment. Due to the ionic character, potassium carbonate has a very low vapour pressure and very high water solubility. Furthermore, bio- and geoaccumulation are not to be expected. Based on this, potassium carbonate will remain predominantly in the water phase.

12.5 Results of PBT and vPvB assessment

Persistence Assessment
Potassium carbonate will rapidly dissolve and dissociate in water. Therefore, potassium carbonate does not fulfil the P criterion.
Bioaccumulation Assessment
Bioaccumulation is not relevant for potassium carbonate, therefore, potassium carbonate does not meet the B criterion of the PBT criteria.
Toxicity Assessment
The lowest reported LC50 for freshwater and marine organisms are above the cut-off value of 0.1 mg/L. Therefore, potassium carbonate does not meet the T criterion in the PBT assessment.
Summary and overall Conclusions on PBT or vPvB Properties
Potassium carbonate does not fulfil the criteria for persistence, bioaccumulation and toxicity. Therefore, this substance is not considered a PBT or a vPvB substance.

12.6 Other adverse effects:
N/A

13. Disposal considerations

13.1 Waste treatment methods

Product / Packaging disposal:
Waste codes / waste designations according to EWC / AVV: N/A

Waste treatment-relevant information: N/A

Other disposal recommendation;

No waste key number as per the European Waste Types List can be assigned to this product, since such classification is based on the (as yet undetermined) use to which the product is put by the consumer. The waste key number must be determined as per the European Waste Types List (decision on EU Waste Types List 2000/532/EC) in cooperation with the disposal firm / producing firm / official authority. Before disposal consult producer. With respect to local regulations, e.g. dispose of to suitable waste incineration plant.

14. Transport Information

14.1 Land transport (ADR/RID):
UN-No.: N/A
Proper shipping name : Potassium carbonate
Class : N/A
Classification Code: N/A
Packing group: N/A
Hazard label(s): N/A
Environmental Hazard: N/A
Special provision(s): N/A

14.2 Inland water ways transport (ADN):
UN-No.: N/A
Proper Shipping Name: Potassium carbonate
Class: N/A
Classification Code: N/A
Packing group: N/A
Environmental Hazardous: N/A
Hazard Label(s): N/A
Special provision(s): N/A

14.3 Sea transport (IMDG Code):
UN-No.: N/A
Proper Shipping Name: Potassium carbonate
Class/es: N/A
Packing group: N/A
Marine Pollutant: no
Special provision(s): N/A

14.4 Air transport (ICAO-TI/IATA-DGR):
UN-No.: N/A
Proper Shipping Name: Potassium carbonate
Class(es): N/A
Packing group: N/A
Special provisions: N/A

14.5 Additional information:
Not classified as dangerous in the meaning of transport regulations.

15. REGULATORY INFORMATION

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

15.1.1 EU regulations Authorisations and/or restrictions on use:
Authorisations: N/A
Restrictions on use: N/A

Other EU regulations:
Informations according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline):

15.1.2 National regulations (Germany)
Restrictions of occupation:
Störfallverordnung (12. BImSchV):
Wassergefährdungsklasse (water hazard class):
Technische Anleitung Luft (TA-Luft):

15.2 Chemical Safety Assessment:
Chemical Safety Assessment has been carried out by the consortium, for potassium carbonate.

16. OTHER INFORMATION

16.1 Indication of changes
Initial date: Dec.01.2010
Revision date: **Version: 1.0**

16.2 Abbreviations and acronyms:
N/A: Not Applicable
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
STOT: Specific target organ toxicity
DNEL: Derived No Effect Level
PNEC: Predicted No Effect Concentration

16.3 Key literature references and sources for data

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16.4 Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Skin Irritation; catergory 2	Based on test data and read across data
Eye Irritation; category 2	Based on test data
STOT Single Exposure; category 3	Based on read across

16.5 Relevant R-, H- and EUH-phrases (number and full text):
R36/37/38 Irritating to eyes, respiratory system and skin
S25 avoid contact with eyes
S26 in case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S36/37/39 wear suitable protective clothing, gloves and eye/face protection

H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation

P261 Avoid breathing dust/ fume/ mist / vapours / spray
P264 Wash hands thoroughly with soap and water after handling
P280 Wear protective gloves/protective clothing/eye protection/face protection
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing
P362 Take off contaminated clothing and wash before reuse
P403+P233 Store in a well-ventilated place Keep container tightly closed

16.6 Training advice:
N/A
16.7 Further information:
N/A

Annex to extended safety data sheet(eSDS)