

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier Cetylpyridinium Chloride, monohydrate
Synonyms: CPC, Cetylpyridinium Chloride, Monohydrate, hexadecylpyridinium chloride
Chemical Abstracts Registry No: 6004-24-6 (123-03-5 for anhydrous)
REACH Registration Number: 01-2120115013-79-0000

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

personal care
used as a pharmaceutical intermediate
Used in xerography
Cationic surfactant

1.3. Details of the supplier of the safety data sheet

Vertellus Health & Specialty Products LLC
215 North Centennial Street
Zeeland, MI 49464-1309 USA
1-800-223-0453

Only Representative for EU REACH Registration:

Vertellus Specialties UK Ltd.
Seal Sands Road, Seal Sands
Middlesbrough, TS2 1UB England
Phone: +44 1642 546 546

e-mail Address: sds@vertellus.com

1.4. Emergency telephone number **Vertellus:** 1-800-223-0453
CHEMTREC (USA): +1-800-424-9300 (collect calls accepted)
CHEMTREC (International): +1-703-527-3887 (collect calls accepted)
NRCC (China): +86 532 83889090

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture (According to Regulation (EC) No 1272/2008, 29 CFR 1910.1200 and the Globally Harmonized System)

Serious Eye Damage Category 1
Environmental Acute Category 1 (M-Factor = 100)
Hazard Not Otherwise Classified - Combustible Dust
Skin Irritation Category 2
Acute Toxicity Oral Category 4
Acute Toxicity Inhalation Dust / Mist Category 2
Specific Target Organ Systemic Toxicity Single Exposure Category 3

2.2. Label elements

Hazard Symbols (Pictogram):



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Signal Word: Danger

Hazard Precautions: H400 - Very toxic to aquatic life.
H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H318 - Causes serious eye damage.
H335 - May cause respiratory irritation.
H330 - Fatal if inhaled.

Prevention Precautionary Statements: P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P284 - Wear respiratory protection.
P270 - Do not eat, drink or smoke when using this product.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.

First Aid Precautionary Statements: P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor/physician.
P362 - Take off contaminated clothing and wash before reuse.
P391 - Collect spillage.

Storage Precautionary Statements: P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

2.3. Other hazards

Other Hazards: WARNING! MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR (DURING PROCESSING). See Section 11 for detailed information about inhalation classification.

SECTION 3: Composition/information on ingredients

3.1. Substances or 3.2. Mixtures

Ingredient	CAS Number	Concentration (weight %)	EC Number	CLP Inventory/Annex VI	EU CLP Classification (1272/2008)
Cetylpyridinium Chloride, monohydrate	6004-24-6	~ 100	204-593-9 (anhydrous)	Not listed.	Aquatic Acute 1; H400 Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Irrit. 2; H315 Acute Tox. 2; H330 STOT SE 3; H335

NOTE: See Section 8 for exposure limit data for these ingredients. See Section 15 for trade secret information (where applicable). See Section 16 for the full text of the R-phrases above.

SECTION 4: First aid measures

4.1. Description of first aid measures

Skin Contact: Immediately flush with water for 15 minutes. Wash the contaminated skin with soap and water. If irritation develops, call a physician.

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Eye Contact:	Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for 15 minutes, or until the chemical is removed. Neutral saline solution may be used as soon as it is available. Take care not to rinse contaminated water into the unaffected eye or onto face. If irritation persists, repeat flushing. Obtain medical attention immediately.
Inhalation:	If exposed to excessive levels remove to fresh air and get medical attention if cough or other symptoms develop. If breathing is difficult, oxygen may be beneficial if administered by trained personnel, preferably on a doctor's advice.
Ingestion:	If swallowed, contact physician or poison control center immediately.

4.2 Most important symptoms and effects, both acute and delayed

Acute:	Inhalation: Irritating to the mucous membranes and respiratory system. Irritation may be severe. Eyes: Direct contact with this product causes serious eye irritation and damage. Serious damage may result if treatment is delayed. May result in permanent corneal injury. Skin: Direct skin contact causes severe irritation. Symptoms include local discomfort or pain, redness and swelling and blister formation. Ingestion: Swallowing can cause irritation to the lips, tongue, throat and digestive tract, abdominal and chest pain, nausea and vomiting.
Delayed Effects:	None known.

4.3. Indication of any immediate medical attention and special treatment needed

Note to Physician:	No specific indications. Treatment should be based on the judgment of the physician in response to the reactions of the patient.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Appropriate Extinguishing Media:	Water spray, Foam, alcohol foam, carbon dioxide, dry chemical.
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5.2. Special hazards arising from the substance or mixture

Hazardous Products of Combustion:	During a fire, irritating and toxic gases, fumes and vapors may be generated. Hydrogen chloride Nitrogen oxides
Potential for Dust Explosion:	Cetylpyridinium Chloride (CPC) was tested for dust explosion characteristics and the following results were obtained: <ul style="list-style-type: none">- minimum ignition energy (MIE): 5 - 10 mJ- Explosion severity - 20L Sphere<ul style="list-style-type: none">- Maximum explosion pressure (bar): 8.5- Maximum rate of pressure rise (bar/s): 682- Kst value (bar.m/s): 185
Special Flammability Hazards:	The MIE data suggests a high sensitivity to ignition. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. Refer to European standards: EN1127-1, EN14491, EN14797, EN14373, and EN15089 for safe handling of and controlling explosive atmospheres in the workplace. This product is an organic solid. As such, in its finely divided form, this product has the potential to present a dust explosion hazard under certain conditions. Please review the dust explosion data enclosed in this section. Handle this product in a manner that prevents dust generation and

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accumulation, and refer to National Fire Protection Association (NFPA) Standard 654 for further information on prevention of dust explosions.

5.3. Advice for firefighters

Basic Fire Fighting Guidance: Wear self-contained breathing apparatus and clothing that will not allow skin contact with material. Water runoff can cause environmental damage. Dike and collect water used to fight fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuation Procedures: Isolate the hazard area and deny entry to unnecessary and unprotected personnel.

Special Instructions: See Section 8 for personal protective equipment recommendations. Remove all contaminated clothing to prevent further absorption. Decontaminate affected personnel using the first aid procedures in Section 4. Leather shoes that have been saturated must be discarded. CPC is extremely irritating to eyes and causes eye damage. Take all precautions needed to avoid eye contact and skin contact.

6.2. Environmental precautions

Prevent releases to soils, drains, sewers and waterways.

6.3. Methods and material for containment and cleaning up

Remove all ignition sources. Ventilate the area of spill or leak. Wear protective equipment during clean-up. Vacuum, scrape or scoop the material into a chemical waste container. After collection of material, flush area with water. Dispose of contents & container in accordance with local, regional, national or international regulations. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Nonsparking tools should be used.

6.4. Reference to other sections

Refer to section 8 for information on selecting personal protective equipment. Refer to section 13 for information on spilled product, absorbent and clean up material disposal instructions.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for Unique Hazards: This material may present a dust explosion hazard in solid form and is sensitive to ignition by electrostatic discharge. Maintain areas below flammable vapor / explosive dust concentrations.

Practices to Minimize Risk: Wear appropriate protective equipment when performing maintenance on contaminated equipment. Wash hands thoroughly before eating or smoking after handling this material. Do not eat, drink or smoke in work areas. Prevent contact with incompatible materials. Avoid spills and keep away from drains. Handle in a manner to prevent generation of aerosols, vapors or dust clouds.

Special Handling Equipment: Not applicable.

7.2. Conditions for safe storage, including any incompatibilities

Storage Precautions & Recommendations: Do not store in direct sunlight. Store in a cool dry place. Keep container closed when not in use. Minimize dust generation and accumulation. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert

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atmospheres. This product should be stored at ambient temperature in a dry, well-ventilated location. Keep away from heat, sparks, and flame

Dangerous Incompatibility Reactions:

Strong oxidizing agents Strong acids. acid anhydrides acid chlorides

Incompatibilities with Materials of Construction:

None known

7.3. Specific end use(s)

If a chemical safety assessment has been completed an exposure scenario is attached as an annex to this Safety Data Sheet. Refer to this annex for the specific exposure scenario control parameters for uses identified in subsection 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Country	Occupational Exposure Limit
Canada - Quebec, Denmark (total dust)	10 mg/m ³ as an 8-hour time-weighted average
China (total dust)	8 mg/m ³ as an 8-hour time-weighted average
Spain (total dust)	0.5 mg/m ³ as an 8-hour time-weighted average
Austria (respirable fraction)	5 mg/m ³ as an 8-hour time-weighted average; 10mg/m ³ short term limit
France, Sweden, USA - OSHA (respirable fraction)	5 mg/m ³ as an 8-hour time-weighted average
Belgium, Spain, Switzerland (respirable fraction)	3 mg/m ³ as an 8-hour time-weighted average
Germany (respirable fraction)	1.5 mg/m ³ as an 8-hour time-weighted average
Hungary (respirable fraction)	6 mg/m ³ as an 8-hour time-weighted average
Ireland (respirable fraction)	4 mg/m ³ as an 8-hour time-weighted average

Air Monitoring Method: Gravimetric analysis for total particulate and respirable fraction (<10 microns).

8.2. Exposure controls

Derived No Effect Levels (DNELs) – Workers:

Route	DNEL
Long-term - systemic effects (inhalation)	No hazard identified
Acute - systemic effects (inhalation)	No hazard identified
Long-term - local effects (inhalation)	High hazard (no threshold derived)
Acute - local effects (inhalation)	High hazard (no threshold derived)
Long-term - systemic effects (dermal)	0.05 mg/kg/bw/day
Acute - systemic effects (dermal)	No hazard identified.
Long term - local effects (dermal)	Medium hazard (no threshold derived)
Acute - local effects (dermal)	Medium hazard (no threshold derived)

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Derived No Effect Levels (DNELs) – General Population:

Route	DNEL
Long-term - systemic effects (oral)	No hazard identified
Long-term - systemic effects (dermal)	No hazard identified
Long-term - systemic effects (inhalation)	No hazard identified
Acute - systemic effects (oral, dermal, inhalation)	No hazard identified
Long-term - local effects (inhalation)	Low hazard (no threshold derived)
Acute - local effects (inhalation)	Low hazard (no threshold derived)
Long term - local effects (dermal)	Low hazard (no threshold derived)
Acute - local effects (dermal)	Low hazard (no threshold derived)

Predicted No Effect Concentrations (PNECs):

Route	PNEC
PNEC aqua (freshwater)	0.0061 ug/L
PNEC aqua (marine water)	0.00061 ug/L
PNEC aqua (intermittent releases)	0.061 ug/L
PNEC aqua (STP)	210 ug/L
PNEC sediment (freshwater)	0.037 mg/kg
PNEC sediment (marine water)	0.0037 mg/kg
PNEC soil	0.0043 mg/kg

Also see the annex to this SDS (if applicable) for specific exposure scenario controls.

- Other Engineering Controls:** All operations should be conducted in well-ventilated conditions. Local exhaust ventilation should be provided. Facilities storing or using this material should be equipped with an eyewash and safety shower. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
- Personal Protective Equipment:** A NIOSH approved chemical cartridge respirator or supplied-air breathing equipment should be used as conditions necessitate. Contact lenses should not be worn when handling this material. Do not smoke or eat in areas where this material is handled. Wear chemical protective gloves and body-covering clothing to prevent skin exposure. Wear chemical goggles. Wear a face-shield when necessary to prevent contact with skin and eyes.
- Respirator Caution:** Observe OSHA regulations for respirator use (29 CFR 1910.134). Air-purifying respirators must not be used in oxygen-deficient atmospheres.
- Thermal Hazards:** Not applicable.
- Environmental Exposure Controls:** The level of protection and types of controls necessary will vary depending upon potential exposure conditions. Select controls based on a risk assessment of local circumstances. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance, State & Odor (ambient temperature):	White to off-white powder/solid with a slight amine odor.		
Molecular Formula:	C ₂₁ H ₃₈ NCl.H ₂ O	Molecular Weight:	358.01
Vapor Pressure:	< 0.0000055 Pa @ 25°C	Evaporation Rate:	No data available.
Specific Gravity or Density:	1.06 @ 20°C	Vapor Density (air = 1):	No data available.
Boiling Point:	120 - 124 °C @ 0.09 hPa	Freezing / Melting Point:	80 - 84 °C
Solubility in Water:	111 g/L @ 20°C	Octanol / Water Coefficient:	Log Kow = 1.71
pH:	5.0 - 5.4 (10 g/L @ 20°C)	Odor Threshold:	No data available.
Viscosity:	Not applicable.	Autoignition Temperature:	>404°C
Flash Point and Method:	No data available.	Flammable Limits:	Not applicable.
Flammability (solid, gas):	Not flammable	Decomposition Temperature:	160 °C
Explosive Properties:	Not explosive	Oxidizing Properties:	Not an oxidizer

9.2. Other information

SECTION 10: Stability and reactivity

<u>10.1. Reactivity</u>	Not classified as dangerously reactive.
<u>10.2. Chemical stability</u>	Stable under normal conditions.
<u>10.3. Possibility of hazardous reactions</u>	Polymerization is not expected to occur
<u>10.4. Conditions to avoid</u>	Avoid contact with incompatible materials, dust generation, and sources of heat
<u>10.5. Incompatible materials</u>	Strong oxidizing agents; Strong acids.; acid anhydrides; acid chlorides
<u>10.6. Hazardous decomposition products</u>	Hydrogen chloride; Nitrogen containing gases; carbon monoxide

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute Oral LD ₅₀ :	560 mg/kg (rat)	Cetylpyridinium Chloride, monohydrate
Acute Dermal LD ₅₀ :	> 5000 mg/kg (rat)	Cetylpyridinium Chloride, monohydrate

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Acute Inhalation LC ₅₀ :	0.05 - 0.51 mg/L (4h, rat)	Cetylpyridinium Chloride, monohydrate (aerosolized)
Skin Irritation:	Moderately irritating to skin.	
Eye Irritation:	Severely irritating to eyes.	
Skin Sensitization:	Negative for sensitizing effects in guinea pig maximization test.	
Mutagenicity:	This product has been shown not to be mutagenic based on a battery of assays.	
Reproductive / Developmental Toxicity:	No data available. Not teratogenic or fetotoxic at levels below those associated with maternal toxicity. In both 28d and 6 month studies in rats & dogs, no evidence of adverse effects on reproductive organs; no effect on fertility.	
Carcinogenicity:	This material is not listed by IARC, NTP or OSHA as a carcinogen. No test data is available that indicates this material is a carcinogen.	
Target Organs:	None known	
Primary Route(s) of Exposure:	Skin contact and absorption, eye contact, and inhalation. Ingestion is not likely to be a primary route of exposure.	
Most important symptoms and effects, both acute and delayed	<p>Inhalation: Irritating to the mucous membranes and respiratory system. Irritation may be severe. Eyes: Direct contact with this product causes serious eye irritation and damage. Serious damage may result if treatment is delayed. May result in permanent corneal injury.</p> <p>Skin: Direct skin contact causes severe irritation. Symptoms include local discomfort or pain, redness and swelling and blister formation.</p> <p>Ingestion: Swallowing can cause irritation to the lips, tongue, throat and digestive tract, abdominal and chest pain, nausea and vomiting. Delayed Effects: None known.</p>	
Additive or Synergistic effects:	None known.	
Additional Toxicity Information:	<p>CPC was tested for inhalation toxicity using finely ground material that had been milled for 24 hours. CPC is never supplied in this finely ground state - typical particle size analysis shows ~2% of the volume by weight is <10 um (respirable fraction). Exposure to the micronized CPC cannot reasonably be expected to occur under normal conditions of shipment and handling, the assignment of hazard class for transportation purposes may also be modified appropriately as per 49 CFR 173.132. Contact SDS@vertellus.com with questions.</p>	

SECTION 12: Ecological information

<u>12.1. Toxicity</u>	<p>LC50 (96h) Oncorhynchus mykiss (rainbow trout) = 0.16 mg/L EC50 (48h) Daphnia magna = 9.65 UG/L (STATIC) EC50 (72h) Selenastrum capricornutum (algae) = 26.9 µg/L NOEC (96-hr) Oncorhynchus mykiss (rainbow trout) = 0.11 mg/L NOEC (72-hr) Selenastrum capricornutum (algae) = 3.2 µg/L NOEC (48-HR) Daphnia magna = 3.2 UG/L (STATIC) EC50 (48h) Daphnia magna = 4.1 µg/L NOEC (48-HR) Daphnia magna = 1.3 UG/L (SEMI-STATIC)</p>	Cetylpyridinium Chloride, monohydrate
<u>12.2. Persistence and degradability</u>	While OECD 301D did not demonstrate "ready biodegradability", an OECD 307 test showed rapid biodegradability; mineralization of 70.7% @ 28 days.	
<u>12.3. Bioaccumulative potential</u>	An estimated BCF of 5.7, based on a calculated Log Kow of 1.71, suggests the potential for bioconcentration in aquatic organisms is low. This is supported by rapid biodegradation results.	
<u>12.4. Mobility in soil</u>	This material is expected to have only slight mobility in soil. It absorbs strongly to most soil types. Quaternary ammonium compounds are known to sorb strongly and rapidly in well-mixed systems, to a	

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wide variety of materials, such as sewage sludge, sediment and clay. This material has been shown sorb readily to activated sludge solids.

12.5. Results of PBT and vPvB assessment

This substance is not a PBT or vPvB.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

US EPA Waste Number:	Non-Hazardous
Waste Classification: (per US regulations)	The waste may be classified as "special" or hazardous per State regulations.
Waste Disposal:	NOTE: Generator is responsible for proper waste characterization. State hazardous waste regulations may differ substantially from federal regulations. Dispose of this material responsibly, and in accordance with standard practice for disposal of potentially hazardous materials as required by applicable international, national, regional, state or local laws, and environmental protection duty of care principles. Do NOT dump into any sewers, on the ground, or into any body of water. For disposal within the EC, the appropriate classification code according to the European Community List of Wastes should be used. Note that disposal regulations may also apply to empty containers and equipment rinsates.

SECTION 14: Transport information

The following information applies to all shipping modes (DOT/IATA/ICAO/IMDG/ADR/RID/ADN), unless otherwise indicated:

14.1. UN number	UN3077	14.2. UN proper shipping name	Environmentally Hazardous Substance, Solid, n.o.s. (Cetylpyridinium Chloride)
14.3. Transport hazard class(es)	9	14.4. Packing group	PG III
14.5. Environmental hazards	Marine Pollutant		
14.6. Special precautions for user	Independent laboratory test results for particle size indicate that CPC does not meet the requirements in 49 CFR 173.132(b)(3)(iii) for a solid substance that is considered a dust. Therefore, acute inhalation data (determined as a dust) is not applicable for determining transportation class. The same requirements apply for international air [2.6.1(c)], maritime [2.6.2.1.3] and ADR (European Agreement concerning the international Carriage of Dangerous Goods [2.2.61.1.3]) transport regulations.		
NA Emergency Guidebook Numbers:	171	IMDG EMS:	S-F; F-A
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code			Consult IMO regulations before transporting in bulk by ocean.

SECTION 15: Regulatory information

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

Chemical Inventory Lists:	Status:		
USA TSCA:	Listed (as anhydrous form, CAS 123-03-5).	EINECS:	204-593-9 (Listed as anhydrous form, CAS 123-03-5).
Canada(DSL/NDL):	DSL (as anhydrous form, CAS 123-03-5).	Japan:	Listed (5-3686)

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Korea:	Listed (99-3-1228, as anhydrous form, CAS 123-03-5)	Australia:	Listed
China:	Listed	Philippines:	Listed
Taiwan:	Listed	New Zealand:	Listed
German Water Hazard Classification:	WGK 3 ((ID# 601, n-Alkyl (C12-16) pyridinium chloride und-bisulfat))		
SARA 313:	Not applicable.		
Reportable Quantities:	Not applicable.		
Other Regulatory Listings:	Certain uses of this substance may be regulated under pesticide/biocidal products regulations.		
HMIS IV:		NFPA:	

HEALTH	3
FLAMMABILITY	0
PHYSICAL HAZARD	0



15.2. Chemical safety assessment

A chemical safety assessment has been prepared for this product.

SECTION 16: Other information

Classification Method: On basis of test data

Legend of Abbreviations:

ACGIH = American Conference on Governmental Industrial Hygienists.

CAS = Chemical Abstracts Service.

CFR = Code of Federal Regulations.

DSL/NDSL = Domestic Substances List/Non-Domestic Substances List.

EC = European Community.

EINECS = European Inventory of Existing Commercial Chemical Substances.

ELINCS = European List of Notified Chemical Substances.

EU = European Union.

GHS = Globally Harmonized System.

LC = Lethal Concentration.

LD = Lethal Dose.

NFPA = National Fire Protection Association.

NIOSH = National Institute of Occupational Safety and Health.

NTP = National Toxicology Program.

OSHA = Occupational Safety and Health Administration

PEL = Permissible Exposure Limit.

RQ = Reportable Quantity.

SARA = Superfund Amendments and Reauthorization Act of 1986.

TLV = Threshold Limit Value.

WHMIS = Workplace Hazardous Materials Information System.

Important Note: Please note that the information contained herein is furnished without warranty of any kind. Users should consider these data only as a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances. The information contained herein may change without prior notice. THIS SAFETY DATA SHEET SUPERSEDES ALL PREVIOUS EDITIONS.

Revision Date:	8 May 2018	Original Date of Issue:	2 Nov 2011
Issued by:	Regulatory Management Department	Email:	SDS@Vertellus.com
Revision Details:	Updated sections for GHS compliance.		

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Annex

Cetylpyridinium Chloride, Monohydrate - Summary of Uses

ES Number	Name	ERC	PROC	PC
ES2	-Formulation of Cosmetic Products	2	1,13	
ES5	Consumer end Use in Cosmetics products	8a		39

Cetylpyridinium Chloride, Monohydrate - Exposure Scenario

Note: Guidance below is in addition to that indicated in sections 1-16 of the SDS

ES2

Title: Formulation of Cosmetic Products

Main Sector of Use Group

- SU3: Industrial uses: Uses of substances as such or in preparations-at industrial sites
 - SU8: Manufacture of bulk, large scale chemicals

Process Categories

- PROC 1: Formulation of Cosmetic products in automated process.
- PROC 13: Impregnation of wipes/tissues in automated process

Environmental Release Categories

ERC 2: Formulation

ES5

Title: Consumer end Use in Cosmetics products

Exposure scenario covering the following

Main Sector of Use Group

Consumer

Consumer Product Categories

- PC 39: Consumer use of cosmetics

Environmental Release Categories

- ERC 6b: Industrial use of reactive processing aids

1. Control of Worker Exposure

Product Characteristic

- Dustiness for solid: Low
- Physical Form: crystals; 100-400 micron diameter; <3% respirable size range of 10 micron

ES	Location	Concentration %
2	Indoor	100
5	indoor	<0.001

Amounts used

- Not relevant for human risk assessment

Frequency and duration of use/exposure, PPE, Ventilation, local exhaust

ES	PROC	Application	Local Exhaust %	Hours /Shift	Respirator	Gloves	Eye	Ventilation
W2	8b	Transfer of Substances-	95	1-4	no	95 %	yes	Enhanced General (5-10)

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		Dedicated Facilities						changes /hr)
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Other given operational conditions affecting workers exposure

- The work is performed indoors

Technical conditions and measures at process level (source) to prevent release:

- See Section 7 of SDSI

Technical conditions and measures to control dispersion from source towards the worker:

- See Section 7 and 8 of SDS
- See Ventilation comments above

Organisational measures to prevent /limit releases, dispersion and exposure: See SDS

- Covers non or low-dusty materials (e.g. pellets, granules, sugar, salt).

Inhalation risks are generally ameliorated through the use of automated, closed formulation systems, however consideration must be given to the slight possibility of fugitive dust formation.

For activities where dust formation may be possible, for example at sites of loading/unloading, Local Exhaust Ventilation (LEV) is recommended. As additional precautions, workers should wear a full-face mask (conforming to EN126) with as suitable particle filter to protect against inhalation risks and contact of irritant dusts with the eye and mucous membranes of the mouth.

Ensure that enough fresh air is supplied to dilute and remove dusts, fumes or vapours. Between 5 and 15 air changes per hour are recommended, with a through draught. Keep good industrial hygiene.

Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if hand contact with substance likely. Clean up contamination/spills as soon as they occur. Wash off any skin contamination immediately. Provide basic employee training to prevent / minimise exposures and to report any skin problems that may develop. Wear suitable coveralls to prevent exposure to the skin.

Avoid direct eye contact with product, also via contamination on hands. Use eye protection according to EN 166, designed to protect against powders and dusts
Automated process with (semi) closed systems.

Control any potential exposure using measures such as contained or enclosed systems, properly designed and maintained facilities and a good standard of general ventilation. Drain down systems and transfer lines prior to breaking containment. Drain down and flush equipment where possible prior to maintenance. Where there is potential for exposure: Ensure relevant staff are informed of the nature of exposure and aware of basic actions to minimise exposures; ensure suitable personal protective equipment is available; clear up spills and dispose of waste in accordance with regulatory requirements; monitor effectiveness of control measures; consider the need for health surveillance; identify and implement corrective actions.

Conditions and measures related to personal protection, hygiene and health evaluation:

- See sections 7, 8 and 10 of SDS
- Respirators: See Table above
- Wear chemically resistant gloves
- Use suitable eye protection

2. Control of Consumer Exposure

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Consumer use of water treatment chemicals (PC37)

Consumer uses e.g. as a carrier in cosmetics/personal care products, perfumes and fragrances. Note: For cosmetic and personal care products, risk assessment only required for the environment under REACH as human health is covered by alternative legislation.

Control of consumer exposure in this assessment covers the consumer use in agrochemicals in liquid and solid forms.

The substance is supplied to consumers in a formulation containing 0.001% CPC, and in child-proof packages not exceeding 10g each. Both solid and liquid formulations are supplied.

The package is designed to be opened and poured into a standard 1L volume of water. After several days, the water is disposed-of, typically through the municipal drainage system.

The risk to consumers is considered to be very low.

Consideration must be given to the possibility of skin irritation should the formulated end-product come into contact with wet skin, as well as the risk of inhalation or eye contact with the solid product.

SCCS considers that the use of cetylpyridinium chloride in cosmetic products for oral and for dermal application is safe for the consumer. Overall, twenty-six oral mucosal irritation tests have been performed from 1969 - 1990. Twelve studies were on CPC concentrations of 0.045% which found it to be generally non-irritating with rinsing conditions, and occasionally mildly irritating in no-rinse groups.

The consumer use under assessment here contains CPC at a concentration of 0.001% w/w, which is further diluted upon use. Although there is a small potential for skin exposure to the solid or liquid forms, and considering the small package size (10mg), there is a negligible risk of skin irritation occurring through the standard use of this product by consumers.

Consumer Use of Cosmetics (PC 39)

Consumer uses e.g. as a carrier in cosmetics/personal care products, perfumes and fragrances. Note: For cosmetic and personal care products, risk assessment only required for the environment under REACH as human health is covered by alternative legislation.

3. Control of Environmental Exposure

Product characteristics

- The substance is a crystal

Frequency and duration of use

- Continuous and Intermittent release possible

ES	Emission days per year	Local Volume per day (kg)	STP Efficiency %	On site water treatment Efficiency %	Application sludge to soil
2	250	400	0	99	No
5	Consumer	wide dispersive use <= 5.5E-2	86.75		

Environment factors not influenced by risk management

- Default values of 18,000 m³/d for receiving waters are assumed
- Discharge rate of STP: 2E5 m³/d

Other given operational conditions affecting environmental exposure

Technical conditions and measures at process level (source) to prevent release

- Equipment cleaning: Equipment cleaning with minimized emissions to wastewater (Typically implemented measures for reducing

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emissions to waste water may include: - Dry cleaning of equipment (Use of absorbent materials and vacuum cleaning including incineration of resulting solid waste) - Cleaning involving so-called pigs - Cleaning involving so-called "cleaning in place" (CIP System) - Steam cleaning and/or - Manual removal of residual products adhering to equipment (e.g. by manual scrubbing, vacuum cleaning, etc.) - use of two-liner systems (i.e. single use disposable reactor cover that is incinerated after use as solid waste))

Water / Air / Soil Release

ES	Air Release Fraction	Water Release Fraction	Soil Release Fraction	Local Release to air (kg/d)	Local release to sewage (kg/d)	Local Release to soil (kg/d)	Criteria
2	0	0.001	0	0	0.004	0	SpERC Cosmetics Europe 2.1a.v2: 1below
5	0.00	1	0.00	0.00	5.5E-4	0.00	SpERC CosmeticEurope8a.1a.v2: 2 below

Description of the technical process covered by the SpERC: Cosmetics Europe 2.1a.v2

- For economic reasons, formulation of mixtures requires minimized losses of raw materials during the mixing and packaging of products. Losses of raw materials via volatilization are negligible. Significant losses to the environment can be the result of cleaning of mixing vessels, tubing, and production/packaging lines. High viscosity products adhere more strongly to the walls of mixing vessels, tubing, and production/packaging lines. They are less efficiently transferred into the packaging. Hence, emissions caused by equipment cleaning are higher and lower for high and low viscosity products, respectively. These losses occur irrespective of the physical-chemical properties of the substance employed in a cosmetic product. For that reason, this SPERC pertains to all substances.

Technical comments

- Before treatment means: emissions as entering an on-site biological WWTP, or if absent, as leaving the site towards a municipal WWTP.
 - It is assumed for simplicity that 1 kg cosmetic product (excl. water) represents ~ 1 kg COD. Actual average value for the chemical ingredients may range from 1-2.
 - Emissions to soil or solid waste are not discussed here, as justified in IFRA (2009), these are considered negligible.
- WARNING:** According to this SPERC, the default daily use amount can be refined from the default. To that end, divide the default value of the amount used locally by a factor of 5 and substitute the result for the default value. In case of refinement, keep only the following explanation: The default value of the amount used locally has been divided by a factor of 5. This is justified by refined information on the consumption pattern of cosmetics and personal care products. According to this information, the Fraction of EU tonnage used in region (FRegion) is 0.053 (default: 0.1) and the Fraction of Regional tonnage used locally (FMainLocalSource) is 0.00075 (default is 0.002).

The environmental exposure calculation per compartment is based on the algorithms of the EU TGD 2003 Risk Assessment Spreadsheet Model 1.24a

Rinse-off products such as shampoo and soap products that are disposed of with the waste water such that 100 % of the product ingredients enter the waste water system. Product residues remaining on the substrate are likely to be washed off in the next washing event

Organizational measures to prevent/limit release from site

- See Sections 6 and 7 of the SDS

Conditions and measures related to municipal sewage treatment plant disposal

- Estimated substance removal from wastewater via STP: 0.04%

Conditions and measures related to external treatment of waste for disposal

- See section 13 of the SDS
- Observe all regional, state and local environmental regulations
- Retain drain downs in sealed storage pending disposal

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Conditions and measures related to external recovery of waste

- There is no recovery at an external waste treatment site

4. Exposure estimation and reference to its source

The ECETOC Targeted Risk Assessment Tool (TRA) version 2.0 was used for the occupational exposure assessment. Details of the TRA may be found in the ECETOC Technical Report No. 93 (2004), and the accompanying Addendum Technical Report No. 107 (2009), or at <https://www.ecetoc-tra.org/>. The assessment of environmental exposure was carried out using EUSES v3.0. Documentation for EUSES 3.0 may be found at <http://ecb.jrc.ec.europa.eu/euses>.

The human health risk assessment and the environmental risk assessment were performed using Chesar with ECETOC TRA 3.0. Tables below summarize the calculated exposures and resulting Risk Characterization Ratios (RCR) at < 1.0. Note the worker exposures in ECETOC TRA are calculated by multiplying the full shift calculations by the following factors:

- >4 hours: 1
- 1-4 hours: 0.6
- 15minutes to 1 hour: 0.2
- < 15minutes: 0.1

5. Guidance to DU - Operational conditions and Risk Management Measures

The activities discussed above result in an acceptable exposure if individually performed by an industrial/professional worker, and considering the operational conditions and the risk management measures (RMM) as defined.

The downstream user may re-calculate the RCR values based on variations in the local operational conditions and application of RMM to confirm that operations are within the control limits.

Predicted Exposure Concentrations / Risk Characterization – Environmental

Compartment	Local PEC; Use 2	RCR*	Local PEC; Use 3	RCR*
Water: Fresh; mg/L	2.387E-6	0.391	6.923E-7	0.114
Water: Fresh Sediment; mg/kg	0.014	0.387	0.0004	0.112
Water: Marine; mg/L	2.388E-7	0.392	6.94E-8	0.114
Water; Marine Sediment; mg/kg	0.001	0.388	4.166E-4	0.113
Water: STP mg/L	0	< 0.1	1.531E-6	<0.01
Soil: mg/kg	5.596E-15	<0.01	1.733E-5	,0.01

Compartment	Local PEC; Use 4	RCR*	Local PEC; Use 5	RCR*
Water: Fresh; mg/L	6.856E-7	0.112	3.896E-6	0.639
Water: Fresh Sediment; mg/kg	0.004	0.111	0.023	0.6321
Water: Marine; mg/L	6.873E-8	0.113	63.898E-7	0.639
Water; Marine Sediment; mg/kg	4.126E-4	0.112	0.002	0.632
Water: STP mg/L	1.458E-6	<0.01	3.645E-5	<0.01
Soil: mg/kg	1.65E-5	<0.01	4.126E-4	0.096

*Risk Characterization Ratio

The default EUSES models show that, despite no risk for Clocal, PEClocal can exceed the RCR at default settings, indicating that exposure estimates are governed by the Regional PEC (PEClocal = Clocal + PECregional).

The regional PEC is derived almost entirely from the consumer end uses. Because the substance will be a component of a down-the-drain consumer products (wash-off, toothpaste, oral rinses), a release rate to water of 100% must be assumed.

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The substance is a chloride salt of a quaternary ammonium compound (QAC) that ionizes in the aquatic milieu, and exhibits surface-active properties. Existing data on the adsorption of CPC to DAF, sludge and soil, show that the substance is very adsorptive, and will have a very high affinity to adsorb on biosolids (van Noorlos, 2008, Herrera 2000).

For industrial formulation activities, it is assumed that automated closed systems are used when handling the substance, and that all waste water is treated in STP equipped with Dissolved Air Flootation (DAF) generator, with a removal efficiency of 99%. Alternatively, biological treatment plants which convert soluble and colloidal materials into biosolids sedimentation (active sludges) will be effective. The removal from municipal STP is typically determined using the SimpleTreat module as part of the EUSES model. The default STP services a population of 10000 inhabitants, treating 2000m³ of domestic waste water. The standard setting of the SimpleTreat module represents an STP with a primary settler (producing primary sludge), an aeration tank (containing activated sludge) and a solids liquid separator (recycling waste sludge back to aeration tank). The model default removal of CPC in municipal STP is approximately 81.5 % via adsorption to sludge. In the default model, 18.5 % of the discharged substance is expected to be released to surface water from the wastewater effluent.

EUSES is a very conservative model that does not account for the very high adsorption of CPC to suspended solids. Based on a kinetics experiment of CPC in 5 soils, the test substance was found to strongly adsorb to the soil. The amount of test substance adsorbed to soil at equilibrium was ≥ 95% for all soils.

From the data collected in the activated sludge sorption isotherm test, it can be concluded that the substance sorbs readily to sludge solids and would, therefore, be efficiently removed from a biological waste water treatment system by clarification.

On this basis, an additional modifying factor for sorption of 99% water treatment efficiency was added to the assessment of environmental exposures from both formulation and consumer end-uses.

As there is no indication of a high bioaccumulation potential, no risk for birds and mammals in the environment via indirect exposure through the food-chain (secondary poisoning) can be expected.

Predicted Exposure Concentrations / Risk Characterization Ratio– Worker

Qualitative assessment was completed to demonstrate control considering alternate modes and the use of defined Operational Conditions and Risk Management Measures for routes other than Long Term Dermal systemic

ES	PROC	Application	Indoors / Outdoors	Hrs/Shift	Dermal systemic LT mg/kg bw/d	Risk Characterization Ratio
W2	8b	Transfer of Substance: dedicated facilities	I	1-4	0.021	0.411
W2	13	Impregnation of wipes / tissues in automated process	I	8	0.007	0.137
W2	19	Professional hand mixing with intimate contact and only PPE available	I	<1	0.283	5.657 See the discussion above