

ES1: Manufacture

1. Title Section		
Manufacture of cetrimonium bromide (CAS 57-09-0)		
(Cetyl Trimethyl Ammonium Bromide (CTAB))		
Environment		
CS 1: Manufacture ERC 1		
Worker		
CS 2: Use in closed system	PROC 1	
CS 3: Use in closed batch process	PROC 3	
CS 4: Transfer of substance/preparations; dedicated facilities	PROC 8b	
CS 5: Transfer of substance/preparations into small containers	PROC 9	

2. Conditions of use affecting exposure

CS 1: Control of environmental exposure: Manufacture (ERC 1)
Amounts used, frequency and duration of use (or from service life)
Daily amount per site: ≤ 0.409 tonnes/day or local release rate (water): 0.008 kg/day
Annual amount per site: < 90 tonnes/year
Frequency and duration of use: 220 days/year
Technical and organisational conditions and measures
No special precautions
Conditions and measures related to sewage treatment plant
Municipal STP: Yes [Effectiveness Water: 93.11%]
• Discharge rate of STP: \geq 2E4 m3/day
Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to treatment of waste
Waste disposal according to national/local legislation is sufficient.
Other conditions affecting environmental exposure
Receiving surface water flow rate: $\geq 1.8E4 \text{ m}3/day$

CS 2: Control of worker exposure: Use in closed system (PROC 1)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Use in closed process

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

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient





CS 3: Control of worker exposure: Use in closed batch process (PROC 3)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 95%]

Closed batch process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 4: Control of worker exposure: Transfer of substance/preparations; dedicated facilities (PROC 8b)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

Semi-closed process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 5: Transfer of substance or preparation into small containers (PROC 9)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

Semi-closed process with occasional controlled exposure

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



Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 1: Environmental release and exposure: Industrial settings, use of intermediates (ERC		
6b)		
Release route	Release rate	Release estimation method
Water	Final release factor: 0.002%	Max release rate
	Local release rate: 0.008 kg/day	
Air	Initial release factor: 0.001%	Release factor
	Final release factor: 0.001%	
	Local release rate: 0.004 kg/day	
	Explanation / Justification: A-table	
	(A1.1) in EU (2003): Technical	
	Guidance Document on Risk	
	Assessment, Part II. MC=3	
Soil	Final release factor: 0.01%	ERC based

Protection target	Exposure estimate	PNEC	RCR
Freshwater	Local PEC: 1.983E-5 mg/L	0.022 µg/L	0.901
Marine water	Local PEC: 8.336E-7 mg/L	0.0022 µg/L	0.379
Agricultural Soil	Local PEC: 0.001 mg/kg dw	0.21 mg/kg	< 0.01
STP	Local PEC: 2.754E-5 mg/L	0.19 mg/L	< 0.01

CS 2: Worker exposure: Use in closed system (PROC 1)			
Route of exposure and type of	Exposure estimate and	DNEL	RCR
effects	method		
Dermal, systemic, acute	-	Long-term systemic de considered sufficiently potential acute effects (toxicological threshol orders of magnitude hi long-term effects).	ermal DNEL is v low to protect against from peak exposure d for acute effects several gher than DNEL for
Dermal, local, acute	-	Short term exposure is by conditions for long- toxicological threshold long-term toxicologica	assessed to be controlled -term, as acute l is 5 times higher than l threshold.
Dermal, systemic, long-term	0.034 mg/kg bw/day (TRA Worker v3)	0.4 mg/kg bw/day	0.085
Dermal, local, long-term	0.01 mg/cm ² (TRA Worker v3)	Exposure is well below threshold of 0.05 mg/c	v the toxicological m ²
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effect controlled, if risk for le	cts is considered ocal effects is controlled



Inhalation, local, acute	0.04 mg/m ³ (TRA Worker	0.05 mg/m ³	0.8
	v3)		
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effect controlled, if risk for le	cts is considered ocal effects is controlled
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below threshold of 0.05 mg/r	v the toxicological n ³
Eye, local		Risk is considered to b wears goggles at any p substance	e controlled if the worker optential eye exposure to
Combined routes, systemic, long-			0.085
term			

CS 3: Worker exposure: Use in closed batch process (PROC 3)			
Route of exposure and type of effects	Exposure estimate and method	DNEL	RCR
Dermal, systemic, acute		Long-term systemic de considered sufficiently potential acute effects (toxicological threshol orders of magnitude hi long-term effects).	ermal DNEL is y low to protect against from peak exposure d for acute effects several igher than DNEL for
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.	
Dermal, systemic, long-term	0.138 mg/kg bw/day (TRA Worker v3)	0.4 mg/kg bw/day	0.345
Dermal, local, long-term	0.04 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²	
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to b wears goggles at any p substance	be controlled if the worker potential eye exposure to
Combined routes, systemic, long- term			0.345

CS 4: Worker exposure: Transfer of substance/preparations; dedicated facilities (PROC			
		DUEL	DOD
Route of exposure and type of	Exposure estimate and	DNEL	RCR
effects	method		
Dermal, systemic, acute		Long-term systemic de considered sufficiently potential acute effects (toxicological threshol orders of magnitude hi long-term effects).	rmal DNEL is y low to protect against from peak exposure d for acute effects several gher than DNEL for



Dermal, local, acute		Short term exposure is by conditions for long toxicological threshold long-term toxicologica	assessed to be controlled -term, as acute 1 is 5 times higher than al threshold.
Dermal, systemic, long-term	0.137 mg/kg bw/day (TRA Worker v3)	0.4 mg/kg bw/day	0.343
Dermal, local, long-term	0.01 mg/cm ² (TRA Worker v3)	Exposure is well below threshold of 0.05 mg/c	w the toxicological cm ²
Inhalation, systemic, acute	0.02 mg/m ³ (TRA Worker v3)	Risk for systemic effect controlled, if risk for h	cts is considered ocal effects is controlled
Inhalation, local, acute	0.02 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.4
Inhalation, systemic, long-term	0.005 mg/m ³ (TRA Worker v3)	Risk for systemic effect controlled, if risk for h	cts is considered ocal effects is controlled
Inhalation, local, long-term	0.005 mg/m ³ (TRA Worker v3)	Exposure is well below threshold of 0.05 mg/r	w the toxicological n ³
Eye, local		Risk is considered to b wears goggles at any p substance	be controlled if the worker potential eye exposure to
Combined routes, systemic, long- term			0.343

CS 5: Worker exposure: Transfer of substance or preparation into small containers (PROC 9)			
Route of exposure and type of effects	Exposure estimate and method	DNEL	RCR
Dermal, systemic, acute		Long-term systemic du considered sufficiently potential acute effects (toxicological threshol orders of magnitude hi long-term effects).	ermal DNEL is y low to protect against from peak exposure ld for acute effects several igher than DNEL for
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.	
Dermal, systemic, long-term	0.137 mg/kg bw/day	0.4 mg/kg	0.343
	(TRA Worker v3)	bw/day	
Dermal, local, long-term	0.02 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²	
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to b wears goggles at any p substance	be controlled if the worker potential eye exposure to
Combined routes, systemic, long- term			0.343





4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Scaling method - Environment
Algorithm
Scalable parameters - Environment
Daily use. Local release rate
Boundaries of scaling -Environment
Do not exceed local release rate

Scaling method - Workers	
TRA Worker v3	
Scalable parameters - Workers	
Daily amounts used per day	
Boundaries of scaling - Workers	
Estimated RCR shall be < 1 to demonstrate safe use	

ABBREVIATIONS		
BW	Body weight	
CS	Contributing Scenario	
DNEL	Derived no-effect level	
DU	Downstream user	
DW	Dry Weight	
ERC	Environmental release category	
ES	Exposure scenario	
PEC	Predicted Exposure Concentrations	
PNEC	Predicted no-effect concentration	
PROC	Process category	
RCR	Risk characterisation ratio	
STP	Sewage treatment plant	
TRA	Targeted Risk Assessment	



ES2: Formulation of laboratory chemicals, cosmetics, pharmaceuticals etc.

1. Title Section			
Formulation with cetrimonium bromide (CAS 57-09-0)			
(Cetyl Trimethyl Ammonium Bromide (CTAB))			
Environment			
CS 1: Formulation	ERC 2		
Worker			
CS 2: Use in closed system	PROC 1		
CS 3: Use in closed system with occasional controlled exposure PROC 2			
CS 4: Mixing and blending operations PROC 5			
CS 5: Transfer of substance/preparations PROC 8a			
CS 6: Transfer of substance/preparations into small containers	PROC 9		

2. Conditions of use affecting exposure

CS 1: Control of environmental exposure: Formulation (ERC 2)		
Amounts used, frequency and duration of use (or from service life)		
Daily amount per site: ≤ 0.1 tonnes/day or local release rate (water): 0.003 kg/day		
Annual amount per site: ≤ 25 tonnes/year		
Frequency and duration of use: 250 days/year		
Technical and organisational conditions and measures		
No special precautions		
Conditions and measures related to sewage treatment plant		
Municipal STP: Yes [Effectiveness Water: 93.11%]		
• Discharge rate of STP: \geq 2E3 m3/day		
Application of the STP sludge on agricultural soil: Yes		
Conditions and measures related to treatment of waste		
Waste disposal according to national/local legislation is sufficient.		
Other conditions affecting environmental exposure		
Receiving surface water flow rate: $\geq 1.8E4 \text{ m}3/day$		

CS 2: Control of worker exposure: Use in closed process (PROC 1)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Use in closed process

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

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor





CS 3: Control of worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Closed continuous process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 4: Mixing and blending operations (PROC 5)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Use Respiratory Protection: Use Respirator with APF of 10 [Effectiveness Inhal: 90%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 5: Transfer of substance or preparation (PROC 8a)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]





Use Respiratory Protection: Use Respirator with APF of 10 [Effectiveness Inhal: 90%] Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 6: Transfer of substance or preparation into small containers (PROC 9)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

Semi-closed process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 1: Environmental release and exposure: Formulation (ERC 2)			
Release route	Release rate	Release estimation method	
Water	Final release factor: 0.003%	Maximum acceptable release	
	Local release rate: 0.003 kg/day	rate in order to keep the RCR	
	Explanation / Justification: This is	below 0.8	
	the maximum daily release rate (per		
	point source) which will keep RCR <		
	0.8		
Air	Initial release factor: 0.25%	Release factor	
	Final release factor: 0.25%		
	Local release rate: 0.25 kg/day	(Formulation release factor (A-	
	Explanation / Justification: A-table	table))	
	(A1.2) in EU (2003): Technical		
	Guidance Document on Risk		
	Assessment, Part II. MC=3, vapour		
	pressure < 10 Pa		
Soil	Final release factor: 0.01%	ERC based	

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Protection target	Exposure estimate	PNEC	RCR
Freshwater	Local PEC: 1.749E-5 mg/L	0.022 μg/L	0.795
Marine water	Local PEC: 1.722E-6 mg/L	0.0022 μg/L	0.783
Agricultural Soil	Local PEC: 0.006 mg/kg dw	0.21 mg/kg dw	0.028
STP	Local PEC: 1.205E-4 mg/L	0.19 mg/L	< 0.01

CS 2: Worker exposure: Use in closed system (PROC 1)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute	-	Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute	-	Short term exposure is by conditions for long- toxicological threshold long-term toxicologica	assessed to be controlled term, as acute is 5 times higher than l threshold.	
Dermal, systemic, long-term	0.034 mg/kg bw/day (TRA	0.4 mg/kg	0.085	
	Worker v3)	bw/day		
Dermal, local, long-term	0.01 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effec controlled, if risk for lo	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8	
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³		
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance		
Combined routes, systemic, long-			0.085	
term				

CS 3: Worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects)		
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.274 mg/kg bw/day (TRA	0.4 mg/kg	0.685	
	Worker v3)	bw/day		





Dermal, local, long-term	0.04 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²	
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long- term		0.685	

CS 4: Worker exposure: Mixing and blending operations (PROC 5)				
Route of exposure and type of effects	Exposure estimate and method	DNEL	RCR	
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.274 mg/kg bw/day (TRA Worker v3)	0.4 mg/kg bw/day	0.686	
Dermal, local, long-term	0.04 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.02 mg/m ³ (TRA Worker v3)	Risk for systemic effect controlled, if risk for lo	ts is considered ocal effects is controlled	
Inhalation, local, acute	0.02 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.4	
Inhalation, systemic, long-term	0.005 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, long-term	0.005 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³		
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance		
Combined routes, systemic, long- term			0.686	





CS 5: Worker exposure: Transfer of substance/ preparations (PROC 8a)				
Route of exposure and type of	Exposure estimate and	DNEL RCR		
effects	method			
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute		Short term exposure is by conditions for long- toxicological threshold long-term toxicological	Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.	
Dermal, systemic, long-term	0.274 mg/kg bw/day (TRA	0.4 mg/kg	0.686	
	Worker v3)	bw/day		
Dermal, local, long-term	0.02 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.02 mg/m ³ (TRA Worker v3)	Risk for systemic effec controlled, if risk for lo	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.02 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.4	
Inhalation, systemic, long-term	0.005 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, long-term	0.005 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³		
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance		
Combined routes, systemic, long-			0.686	
term				

CS 6: Worker exposure: Transfer of substance or preparation into small containers (PROC 9)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.137 mg/kg bw/day (TRA	0.4 mg/kg	0.343	
	Worker v3)	bw/day		
Dermal, local, long-term	0.02 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8	
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker	Exposure is well below	the toxicological	



	v3)	threshold of 0.05 mg/m	1 ³
Eye, local		Risk is considered to b wears goggles at any p substance	e controlled if the worker otential eye exposure to
Combined routes, systemic, long-			0.343
term			

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Scaling method - Environment Algorithm Scalable parameters - Environment

Daily use. Local release rate

Boundaries of scaling -Environment

Do not exceed local release rate

Scaling method - Workers
TRA Worker v3
Scalable parameters - Workers
Daily amounts used per day
Boundaries of scaling - Workers
Estimated RCR shall be < 1 to demonstrate safe use

ABBREVIATIONS		
BW	Body weight	
CS	Contributing Scenario	
DNEL	Derived no-effect level	
DU	Downstream user	
DW	Dry Weight	
ERC	Environmental release category	
ES	Exposure scenario	
PEC	Predicted Exposure Concentrations	
PNEC	Predicted no-effect concentration	
PROC	Process category	
RCR	Risk characterisation ratio	
STP	Sewage treatment plant	
TRA	Targeted Risk Assessment	



ES3: Formulation of articles with cosmetics, pharmaceuticals (e.g. wet wipes, tablets)

1. Title Section	
Formulation of articles with cetrimonium bromide (CAS 57-09-0)	
(Cetyl Trimethyl Ammonium Bromide (CTAB))	
Environment	
CS 1: Formulation in materials	ERC 3
Worker	
CS 2: Use in closed process, no likelihood of exposure	PROC 1
CS 3: Use in closed, continuous process with occasional controlled	PROC 2
exposure	
CS 4: Mixing or blending in batch processes for formulation of	PROC 5
preparations and articles (multistage and/or significant contact)	
CS 5: Transfer of substance or preparation (charging/discharging)	PROC 8a
from/to vessels/large containers at non-dedicated facilities	
CS 6: Transfer of substance or preparation into small containers	PROC 9
(dedicated filling line, including weighing)	
CS 7: Production of preparations or articles by tabletting, compression,	PROC 14
extrusion, pelletisation	

2. Conditions of use affecting exposure

CS 1: Control of environmental exposure: Formulation in materials (ERC 3)
Amounts used, frequency and duration of use (or from service life)
Daily amount per site: $\leq 8 \text{ kg/day}$ or local release rate (Water): 0.003 kg/day
Annual amount per site: ≤ 2 tonnes/year
Frequency and duration of use: 250 days/year
Technical and organisational conditions and measures
No special precautions
Conditions and measures related to sewage treatment plant
Municipal STP: Yes [Effectiveness Water: 93.11%]
Discharge rate of STP: \geq 2E3 m3/day
Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to treatment of waste
Waste disposal according to national/local legislation is sufficient.
Other conditions affecting environmental exposure
Receiving surface water flow rate: \geq 1.8E4 m3/day

CS 2: Control of worker exposure: Use in closed process (PROC 1)

Product (article) characteristics

Substance as such. High dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures



General ventilation: Basic general ventilation (1-3 air changes per hour)

Use in closed process

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

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 3: Control of worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Closed continuous process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 4: Control of worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (PROC 5)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient



CS 5: Control of worker exposure: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 6: Control of worker exposure: Transfer of substance or preparation into small containers (PROC 9)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

Semi-closed process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 7: Control of worker exposure: Production of preparations or articles by tabletting, compression, extrusion, pelletisation (PROC 14)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]



Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 1: Environmental release and exposure: Formulation in materials (ERC 3)			
Release route	Release rate	Release estimation method	
Water	Final release factor: 0.044%	Maximum acceptable release	
	Local release rate: 0.003 kg/day	rate in order to keep the RCR	
	Explanation / Justification: This is	below 0.8	
	the maximum daily release rate (per		
	point source) which will keep RCR <		
	0.8		
Air	Initial release factor: 0.25%	Release factor	
	Final release factor: 0.25%		
	Local release rate: 0.02 kg/day		
Soil	Final release factor: 0.1%	ERC based	

Protection target	Exposure estimate	PNEC	RCR
Freshwater	Local PEC: 1.749E-5 mg/L	0.022 μg/L	0.795
Marine water	Local PEC: 1.722E-6 mg/L	0.0022 µg/L	0.783
Agricultural Soil	Local PEC: 0.005 mg/kg dw	0.21 mg/kg	0.023
STP	Local PEC: 1.205E-4 mg/L	0.19 mg/L	< 0.01

CS 2: Worker exposure: Use in closed process (PROC 1)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute	-	Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute	-	Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.034 mg/kg bw/day (TRA	0.4 mg/kg	0.085	
	Worker v3)	bw/day		
Dermal, local, long-term	0.01 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8	
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker	Risk for systemic effec controlled, if risk for lo	ts is considered ocal effects is controlled	



	v3)		
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker	Exposure is well below the toxicological threshold of 0.05 mg/m^3	
	v3)	uneshold of 0.05 mg/f	•
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long-			0.085
term			

CS 3: Worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.274 mg/kg bw/day (TRA	0.4 mg/kg	0.685	
	Worker v3)	bw/day		
Dermal, local, long-term	0.04 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8	
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³		
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance		
Combined routes, systemic, long- term			0.685	

CS 4: Worker exposure: Mixing or blending in batch processes for formulation of preparations and articles (PROC 5)			
Route of exposure and type of	Exposure estimate and	DNEL	RCR
effects	method		
Dermal, systemic, acute		Long-term systemic de sufficiently low to prot effects from peak expo threshold for acute effe magnitude higher than effects).	rmal DNEL is considered ect against potential acute sure (toxicological ects several orders of DNEL for long-term
Dermal, local, acute		Short term exposure is by conditions for long- toxicological threshold long-term toxicologica	assessed to be controlled term, as acute is 5 times higher than l threshold.





Dermal, systemic, long-term	0.274 mg/kg bw/day (TRA	0.4 mg/kg	0.686
	Worker v3)	bw/day	
Dermal, local, long-term	0.04 mg/cm ² (TRA Worker	Exposure is well below threshold of 0.05 mg/c	the toxicological m^2
	v3)	uneshold of oldering e	
Inhalation, systemic, acute	0.02 mg/m ³ (TRA Worker	Risk for systemic effec	ts is considered
	v3)	controlled, if fisk for it	cal effects is controlled
Inhalation, local, acute	0.02 mg/m ³ (TRA Worker	0.05 mg/m ³	0.4
	v3)		
Inhalation, systemic, long-term	0.005 mg/m ³ (TRA	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
	Worker v3)		
Inhalation, local, long-term	0.005 mg/m ³ (TRA	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
	Worker v3)		
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long-			0.686
term			

CS 5: Worker exposure: Transfer of substance or preparation (charging/discharging) from/to				
vessels/large containers at non-dedicated facilities (PROC 8a)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.274 mg/kg bw/day (TRA	0.4 mg/kg	0.686	
	Worker v3)	bw/day		
Dermal, local, long-term	0.02 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.02 mg/m ³ (TRA Worker v3)	Risk for systemic effect controlled, if risk for lo	ets is considered local effects is controlled	
Inhalation, local, acute	0.02 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.4	
Inhalation, systemic, long-term	0.005 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, long-term	0.005 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³		
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance		
Combined routes, systemic, long-			0.686	
term				





CS 6: Worker exposure: Transfer of substance or preparation into small containers (PROC 9)			
Route of exposure and type of	Exposure estimate and	DNEL RCR	
effects	method		
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).	
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.	
Dermal, systemic, long-term	0.137 mg/kg bw/day (TRA	0.4 mg/kg	0.343
	Worker v3)	bw/day	
Dermal, local, long-term	0.02 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²	
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long-			0.343
term			

CS 7: Worker exposure: Production of preparations or articles by tabletting, compression,				
extrusion, pelletisation (PROC 14)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute		Long-term systemic de sufficiently low to prot effects from peak expo threshold for acute effe magnitude higher than effects).	rmal DNEL is considered ect against potential acute sure (toxicological ects several orders of DNEL for long-term	
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.069 mg/kg bw/day (TRA	0.4 mg/kg	0.172	
	Worker v3)	bw/day		
Dermal, local, long-term	0.01 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker	0.05 mg/m ³	0.8	
	v3)			
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker	Risk for systemic effect controlled, if risk for lo	ts is considered ocal effects is controlled	



	v3)		
Eye, local		Risk is considered to be	e controlled if the worker
		substance	stential eye exposure to
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker	Exposure is well below the toxicological $\frac{1}{2}$	
	v3)	unreshold of 0.03 mg/m	
Combined routes, systemic, long-			0.172
term			

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Scaling method - Environment Algorithm Scalable parameters - Environment

Daily use. Local release rate

Boundaries of scaling -Environment

Do not exceed local release rate

 Scaling method - Workers

 TRA Worker v3

 Scalable parameters - Workers

 Daily amounts used per day

 Boundaries of scaling - Workers

 Estimated RCR shall be < 1 to demonstrate safe use</td>

ABBREVIATIONS		
BW	Body weight	
CS	Contributing Scenario	
DNEL	Derived no-effect level	
DU	Downstream user	
DW	Dry Weight	
ERC	Environmental release category	
ES	Exposure scenario	
PEC	Predicted Exposure Concentrations	
PNEC	Predicted no-effect concentration	
PROC	Process category	
RCR	Risk characterisation ratio	
STP	Sewage treatment plant	
TRA	Targeted Risk Assessment	



ES4: Use at industrial site - Use of Phase Transfer Catalysts

1. Title Section		
Industrial use of cetrimonium bromide (CAS 57-09-0) – use of phase trans	sfer catalysts	
(Cetyl Trimethyl Ammonium Bromide (CTAB))		
Environment		
CS 1: Industrial settings, use of intermediates	ERC 6b	
Worker		
CS 2: Use in closed system	PROC 1	
CS 3: Use in closed system with occasional controlled exposure	PROC 2	
CS 4: Use in closed batch process	PROC 3	
CS 5: Use in batch system with occasional controlled exposure	PROC 4	
CS 6: Transfer of mixture	PROC 8a	
CS 7: Transfer of substance/preparations; dedicated facilities	PROC 8b	
CS 8: Transfer of substance/preparations into small containers	PROC 9	

2. Conditions of use affecting exposure

CS 1: Control of environmental exposure: Use at industrial site - Use of Phase Transfer Catalysts (ERC 6b)

Amounts used, frequency and duration of use (or from service life)

Daily amount per site: ≤ 0.008 tonnes/day or local release rate (water): 0.003 kg/day

Annual amount per site: ≤ 2 tonnes/year

Frequency and duration of use: 250 days/year

Technical and organisational conditions and measures

No special precautions

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 93.11%]

• Discharge rate of STP: \geq 2E3 m3/day

• Application of the STP sludge on agricultural soil: Yes

Conditions and measures related to treatment of waste

Waste disposal according to national/local legislation is sufficient.

Other conditions affecting environmental exposure

Receiving surface water flow rate: $\geq 1.8E4 \text{ m3/day}$

CS 2: Control of worker exposure: Use in closed system (PROC 1)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Use in closed process





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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 3: Control of worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Closed continuous process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 4: Control of worker exposure: Use in closed batch process (PROC 3)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

Closed batch process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 5: Control of worker exposure: Use in batch system with occasional controlled exposure (PROC 4)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use



< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

Semi-closed process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Use Respiratory Protection: Use Respirator with APF of 10 [Effectiveness Inhal: 90%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 6: Control of worker exposure: Transfer of mixture (PROC 8a)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Use Respiratory Protection: Use Respirator with APF of 10 [Effectiveness Inhal: 90%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 7: Control of worker exposure: Transfer of substance/preparations; dedicated facilities (PROC 8b)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 95%]

Semi-closed process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor





Process temperature (for solid): Ambient

CS 8: Transfer of substance or preparation into small containers (PROC 9)

Product (article) characteristics

Substance as such. Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: Yes [Effectiveness Inhal: 90%]

Semi-closed process with occasional controlled exposure

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient

CS 1: Environmental release and exposure: Industrial settings, use of intermediates (ERC 6b)			
Release route	Release rate	Release estimation method	
Water	Final release factor: 0.044%	Maximum acceptable release	
	Local release rate: 0.003 kg/day	rate in order to keep the RCR	
	Explanation / Justification: This is	below 0.8	
	the maximum daily release rate (per		
	point source) which will keep RCR <		
	0.8		
Air	Initial release factor: 0.1%	ERC based	
	Final release factor: 0.1%		
	Local release rate: 0.008 kg/day		
Soil	Final release factor: 0.025%	ERC based	

Protection target	Exposure estimate	PNEC	RCR
Freshwater	Local PEC: 1.749E-5 mg/L	0.022 μg/L	0.795
Marine water	Local PEC: 1.722E-6 mg/L	0.0022 µg/L	0.783
Agricultural Soil	Local PEC: 0.005 mg/kg dw	0.21 mg/kg	0.023
STP	Local PEC: 1.205E-4 mg/L	0.19 mg/L	< 0.01



CS 2: Worker exposure: Use in closed system (PROC 1)			
Route of exposure and type of	Exposure estimate and	DNEL RCR	
effects	method		
Dermal, systemic, acute	-	Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).	
Dermal, local, acute	-	Short term exposure is by conditions for long- toxicological threshold long-term toxicological	assessed to be controlled term, as acute is 5 times higher than threshold.
Dermal, systemic, long-term	0.007 mg/kg bw/day (TRA	0.4 mg/kg	0.017
	Worker v3)	bw/day	
Dermal, local, long-term	0.002 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²	
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long-			0.017
term			

CS 3: Worker exposure: Use in closed, continuous process with occasional controlled exposure (PROC 2)

cxposure (1 KOC 2)			
Route of exposure and type of	Exposure estimate and	DNEL	RCR
effects	method		
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).	
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.	
Dermal, systemic, long-term	0.274 mg/kg bw/day (TRA Worker v3)	0.4 mg/kg bw/day	0.685
Dermal, local, long-term	0.04 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²	
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8



Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to be wears goggles at any p substance	e controlled if the worker otential eye exposure to
Combined routes, systemic, long-			0.685
term			

CS 4: Worker exposure: Use in closed batch process (PROC 3)			
Route of exposure and type of effects	Exposure estimate and method	DNEL	RCR
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).	
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.	
Dermal, systemic, long-term	0.138 mg/kg bw/day (TRA Worker v3)	0.4 mg/kg bw/day	0.345
Dermal, local, long-term	0.04 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²	
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effec controlled, if risk for lo	ts is considered local effects is controlled
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long- term			0.345

CS 5: Worker exposure: Use in batch system with occasional controlled exposure (PROC 4)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute		Short term exposure is by conditions for long- toxicological threshold long-term toxicologica	assessed to be controlled term, as acute is 5 times higher than l threshold.	





Dermal, systemic, long-term	0.137 mg/kg bw/day (TRA	0.4 mg/kg	0.343
	Worker v3)	bw/day	
Dermal, local, long-term	0.02 mg/cm ² (TRA Worker	Exposure is well below the toxicological threshold of 0.05 mg/cm ²	
	V3)		
Inhalation, systemic, acute	0.02 mg/m ³ (TRA Worker	Risk for systemic effec	ts is considered
	v3)	controlled, if risk for lo	cal effects is controlled
Inhalation, local, acute	0.02 mg/m ³ (TRA Worker	0.05 mg/m ³	0.4
	v3)		
Inhalation, systemic, long-term	0.005 mg/m ³ (TRA	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
	worker v3)		
Inhalation, local, long-term	0.005 mg/m ³ (TRA	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
	Worker v3)		
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long-			0.343
term			

CS 6: Worker exposure: Transfer of mixture (PROC 8a)				
Route of exposure and type of effects	Exposure estimate and method	DNEL	RCR	
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.274 mg/kg bw/day (TRA Worker v3)	0.4 mg/kg bw/day	0.686	
Dermal, local, long-term	0.02 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.02 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, acute	0.02 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.4	
Inhalation, systemic, long-term	0.005 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, long-term	0.005 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³		
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance		
Combined routes, systemic, long- term			0.686	





CS 7: Worker exposure: Transfer of substance/preparations; dedicated facilities (PROC 8b)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.137 mg/kg bw/day (TRA	0.4 mg/kg	0.343	
	Worker v3)	bw/day		
Dermal, local, long-term	0.01 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.02 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, acute	0.02 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.4	
Inhalation, systemic, long-term	0.005 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, long-term	0.005 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³		
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance		
Combined routes, systemic, long- term			0.343	

CS 8: Worker exposure: Transfer of substance or preparation into small containers (PROC 9)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute		Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute		Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.137 mg/kg bw/day (TRA Worker v3)	0.4 mg/kg bw/day	0.343	
Dermal, local, long-term	0.02 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		
Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled		
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8	
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker	Risk for systemic effects is considered controlled, if risk for local effects is controlled		



	v3)		
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long-			0.343
term			

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Scaling method - Environment Algorithm Scalable parameters - Environment Daily use. Local release rate Boundaries of scaling -Environment

Do not exceed local release rate

Scaling method - Workers
TRA Worker v3
Scalable parameters - Workers
Daily amounts used per day
Boundaries of scaling - Workers
Estimated RCR shall be < 1 to demonstrate safe use

ABBREVIATIONS		
BW	Body weight	
CS	Contributing Scenario	
DNEL	Derived no-effect level	
DU	Downstream user	
DW	Dry Weight	
ERC	Environmental release category	
ES	Exposure scenario	
PEC	Predicted Exposure Concentrations	
PNEC	Predicted no-effect concentration	
PROC	Process category	
RCR	Risk characterisation ratio	
STP	Sewage treatment plant	
TRA	Targeted Risk Assessment	



ES5: Use by professional worker - Professional use of cosmetics and personal care products

Professional use of cetrimonium bromide (CAS 57-09-0), SU 20: Health services		

2. Conditions of use affecting exposure

CS 1: Use by professional worker (ERC 8a)
Amounts used, frequency and duration of use (or from service life)
Daily wide dispersive use: ≤ 8.2 E-7 tonnes/day or local release rate (water): 8.2E-4 kg/day
Γotal tonnage: 6 tonnes/year; Regional level: 0.6 tonnes/year
Frequency and duration of use: 365 days/year
Fechnical and organisational conditions and measures
No special precautions
Conditions and measures related to sewage treatment plant
Municipal STP: Yes [Effectiveness Water: 93.11%]
• Discharge rate of STP: \geq 2E3 m3/day
Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to treatment of waste
Waste disposal according to national/local legislation is sufficient.

Other conditions affecting environmental exposure

Receiving surface water flow rate: $\geq 1.8E4 \text{ m}3/day$

CS 2: Control of worker exposure: Hand mixing (PROC 19)

Product (article) characteristics

Solid in solid mixtures

Concentration of substance in mixture: <1%

Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: yes [Effectiveness Inhal: 80%]

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

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient



3. Exposure and risk estimation

CS 1: Environmental release and exposure: Use by professional worker (ERC 8a)			
Release route	Release rate	Release estimation method	
Water	Initial release factor: 100%	ERC based	
	Final release factor: 100%		
	Local release rate: 8.2E-4		
	kg/day		
Air	Initial release factor: 0%	Release factor	
	Final release factor: 0%		
Soil	Final release factor: 0%	ERC based	

Protection target	Exposure estimate	PNEC	RCR
Freshwater	Local PEC: 8.675E-6 mg/L	0.022 µg/L	0.394
Marine water	Local PEC: 8.402E-7 mg/L	0.0022 µg/L	0.382
Agricultural Soil	Local PEC: 0.001 mg/kg dw	0.21 mg/kg	< 0.01
STP	Local PEC: 2.823E-5 mg/L	0.19 mg/L	< 0.01

CS 2: Worker exposure: Hand mixing (PROC 19)				
Route of exposure and type of	Exposure estimate and	DNEL	RCR	
effects	method			
Dermal, systemic, acute	-	Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).		
Dermal, local, acute	-	Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.		
Dermal, systemic, long-term	0.28 mg/kg bw/day (External Tool (Based on ECETOC Tra)) ¹	0.4 mg/kg bw/day	0.7	
Dermal, local, long-term	0.01 mg/cm ² (External Tool (Based on ECETOC Tra)) ²	Exposure is well below the toxicological threshold of 0.05 mg/cm ²		

 ¹ Dermal, systemic, long-term: ECETOC TRA predicts 28.29 mg/kg bw/d for 8 hr exposure to 100% substance. We assumed that exposure is proportional to concentration, which is set to 1% => 0.28 mg/kg bw/d

• ² Dermal, local, long-term: ECETOC TRA predicts 1 mg/cm2 for 8 hr exposure to 100% substance. We assumed that exposure is proportional to concentration, which is set to 1% => 0.01 mg/cm2





Inhalation, systemic, acute	0.04 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.04 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.8
Inhalation, systemic, long-term	0.01 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, long-term	0.01 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long- term			0.7

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Scaling method - Environment

Algorithm

Scalable parameters - Environment

Daily use. Local release rate

Boundaries of scaling -Environment

Do not exceed local release rate

Scaling method - Workers

TRA Worker v3

Scalable parameters - Workers

Daily amounts used per day. Concentration in mixture

Boundaries of scaling - Workers

Estimated RCR shall be < 1 to demonstrate safe use



ABBREVIATIONS		
BW	Body weight	
CS	Contributing Scenario	
DNEL	Derived no-effect level	
DU	Downstream user	
DW	Dry Weight	
ERC	Environmental release category	
ES	Exposure scenario	
PEC	Predicted Exposure Concentrations	
PNEC	Predicted no-effect concentration	
PROC	Process category	
RCR	Risk characterisation ratio	
STP	Sewage treatment plant	
SU	Sector of Use	
TRA	Targeted Risk Assessment	

ES6: Use by professional worker - Professional use of laboratory chemicals

Professional use of cetrimonium bromide (CAS 57-09-0), laboratory chemicals		
(Cetyl Trimethyl Ammonium Bromide (CTAB))		
ERC 8a		
PROC 15		

2. Conditions of use affecting exposure

CS 1: Use by professional worker (ERC 8a)

Amounts used, frequency and duration of use (or from service life)

Daily wide dispersive use: ≤ 1.4E-7 tonnes/day or local release rate (water): 1.4E-4 kg/day

Total tonnage: 1 tonnes/year; Regional level: 0.1 tonnes/year

Frequency and duration of use: 365 days/year

Technical and organisational conditions and measures

No special precautions

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 93.11%]

• Discharge rate of STP: \geq 2E3 m3/day

• Application of the STP sludge on agricultural soil: Yes

Conditions and measures related to treatment of waste

Waste disposal according to national/local legislation is sufficient.

Other conditions affecting environmental exposure

Receiving surface water flow rate: $\geq 1.8E4 \text{ m}3/day$

CS 2: Control of worker exposure: Use as laboratory reagent (PROC 15)

Product (article) characteristics

Solid in solid mixtures

Concentration of substance in mixture: <1%

Low dustiness

Amounts used, frequency and duration of use

< 8 hours/day

Technical and organisational conditions and measures

General ventilation: Basic general ventilation (1-3 air changes per hour)

Local exhaust ventilation: yes [Effectiveness Inhal: 80%]

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

Use chemically resistant gloves conforming to EN374 [Effectiveness Dermal: 80%]

Wear goggles/face shield if there is the slightest risk of exposure.

Other conditions affecting workers exposure

Place of use: Indoor

Process temperature (for solid): Ambient



CS 1: Environmental release and exposure: Use by professional worker (ERC 8a)			
Release route	Release rate	Release estimation method	
Water	Initial release factor: 100%	ERC based	
	Final release factor: 100%		
	Local release rate: 1.4E-4 kg/day		
Air	Initial release factor: 0%	Release factor	
	Final release factor: 0%		
Soil	Final release factor: 0%	ERC based	

Protection target	Exposure estimate	PNEC	RCR
Freshwater	Local PEC: 6.438E-6 mg/L	0.022 µg/L	0.293
Marine water	Local PEC: 6.164E-7 mg/L	0.0022 µg/L	0.28
Agricultural Soil	Local PEC: 1.904E-4 mg/kg	0.21 mg/kg	< 0.01
	dw		
STP	Local PEC: 4.82E-6 mg/L	0.19 mg/L	< 0.01

CS 2: Worker exposure: Use as laboratory reagent (PROC 15)			
Route of exposure and type of	Exposure estimate and	DNEL	RCR
effects	method		
Dermal, systemic, acute	-	Long-term systemic dermal DNEL is considered sufficiently low to protect against potential acute effects from peak exposure (toxicological threshold for acute effects several orders of magnitude higher than DNEL for long-term effects).	
Dermal, local, acute	-	Short term exposure is assessed to be controlled by conditions for long-term, as acute toxicological threshold is 5 times higher than long-term toxicological threshold.	
Dermal, systemic, long-term	0.007 mg/kg bw/day (TRA	0.4 mg/kg	0.017
	Worker v3)	bw/day	
Dermal, local, long-term	0.002 mg/cm ² (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/cm ²	
Inhalation, systemic, acute	0.008 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, acute	0.008 mg/m ³ (TRA Worker v3)	0.05 mg/m ³	0.16
Inhalation, systemic, long-term	0.002 mg/m ³ (TRA Worker v3)	Risk for systemic effects is considered controlled, if risk for local effects is controlled	
Inhalation, local, long-term	0.002 mg/m ³ (TRA Worker v3)	Exposure is well below the toxicological threshold of 0.05 mg/m ³	
Eye, local		Risk is considered to be controlled if the worker wears goggles at any potential eye exposure to substance	
Combined routes, systemic, long-			0.017
term			



4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Scaling method - Environment

Algorithm

Scalable parameters - Environment

Daily use. Local release rate

Boundaries of scaling -Environment

Do not exceed local release rate

Scaling method - Workers
TRA Worker v3
Scalable parameters - Workers
Daily amounts used per day. Concentration in mixture
Boundaries of scaling - Workers
Estimated RCR shall be < 1 to demonstrate safe use

ABBREVIATIONS		
BW	Body weight	
CS	Contributing Scenario	
DNEL	Derived no-effect level	
DU	Downstream user	
DW	Dry Weight	
ERC	Environmental release category	
ES	Exposure scenario	
PEC	Predicted Exposure Concentrations	
PNEC	Predicted no-effect concentration	
PROC	Process category	
RCR	Risk characterisation ratio	
STP	Sewage treatment plant	
TRA	Targeted Risk Assessment	





ES7: Consumer Use - Consumer use of cosmetics, perfumes and personal products indoor and outdoor

1. Title Section	
Consumer use of cetrimonium bromide (CAS 57-09-0), indoor and outdoor	or.
(Cetyl Trimethyl Ammonium Bromide (CTAB))	
Environment	
CS 1: Consumer use, indoor	ERC 8d, ERC 8a

2. Conditions of use affecting exposure

CS 1: Control of environmental exposure: Consumer use, indoor (ERC 8d, ERC 8a)

Amounts used, frequency and duration of use (or from service life)

Daily wide dispersive use: \leq 2E-6 tonnes/day or local release rate (water): 0.002 kg/day

Total tonnage: 16 tonnes/year; Regional level: 1.6 tonnes/year

Frequency and duration of use: 365 days/year

Technical and organisational conditions and measures

No special precautions

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 93.11%]

• Discharge rate of STP: \geq 2E3 m3/day

• Application of the STP sludge on agricultural soil: Yes

Conditions and measures related to treatment of waste

Waste disposal according to national/local legislation is sufficient.

Other conditions affecting environmental exposure

Receiving surface water flow rate: $\geq 1.8E4 \text{ m3/day}$

CS 1: Environmental release and exposure: Consumer use, indoor (ERC 8d, ERC 8a)			
Release route	Release rate	Release estimation method	
Water	Initial release factor: 100%	ERC based	
	Final release factor: 100%		
	Local release rate: 0.002 kg/day		
Air	Initial release factor: 0%	Release factor	
	Final release factor: 0%		
Soil	Final release factor: 20%	ERC based	

Protection target	Exposure estimate	PNEC	RCR
Freshwater	Local PEC: 1.256E-5 mg/L	0.022 μg/L	0.571
Marine water	Local PEC: 1.228E-6 mg/L	0.0022 µg/L	0.558
Agricultural Soil	Local PEC: 0.003 mg/kg dw	0.21 mg/kg	0.013



4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Scaling method - Environment
Algorithm
Scalable parameters - Environment
Daily use. Local release rate
Boundaries of scaling -Environment
Do not exceed local release rate

ABBREVIATIONS		
BW	Body weight	
CS	Contributing Scenario	
DNEL	Derived no-effect level	
DU	Downstream user	
DW	Dry Weight	
ERC	Environmental release category	
ES	Exposure scenario	
PEC	Predicted Exposure Concentrations	
PNEC	Predicted no-effect concentration	
PROC	Process category	
RCR	Risk characterisation ratio	
STP	Sewage treatment plant	
TRA	Targeted Risk Assessment	



ES8: Service life (consumers) - Consumer and professional indoor use of cosmetics in wet wipes

1. Title Section		
Service life from consumer use of cetrimonium bromide (CAS 57-09-0)		
(Cetyl Trimethyl Ammonium Bromide (CTAB))		
Environment		
CS 1: Consumer use indoor, cosmetics, pharmaceuticals in articles	ERC 11a	

2. Conditions of use affecting exposure

CS 1: Control of environmental exposure: Consumer use indoor, cosmetics, pharmaceuticals in articles (ERC 11a)

Amounts used, frequency and duration of use (or from service life)

Daily wide dispersive use: $\leq 2.7E-7$ tonnes/day or local release rate (water): 1.35E-7 kg/day

Total tonnage: 2 tonnes/year; Regional level: 0.2 tonnes/year

Frequency and duration of use: 365 days/year

Technical and organisational conditions and measures

No special precautions

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 93.11%]

• Discharge rate of STP: \geq 2E3 m3/day

• Application of the STP sludge on agricultural soil: Yes

Conditions and measures related to treatment of waste

Waste disposal according to national/local legislation is sufficient.

Other conditions affecting environmental exposure

Receiving surface water flow rate: $\geq 1.8E4 \text{ m}3/day$

CS 1: Environmental release and exposure: Consumer use, indoor (ERC 8d, ERC 8a)				
Release route	Release rate	Release estimation method		
Water	Initial release factor: 0.05%	ERC based		
	Final release factor: 0.05%			
	Local release rate: 1.35E-7 kg/day			
Air	Initial release factor: 0%	Release factor		
	Final release factor: 0%			
Soil	Final release factor: 0%	ERC based		



PNEC Protection target Exposure estimate RCR Local PEC: 5.978E-6 mg/L 0.022 µg/L 0.272 Freshwater Marine water **Local PEC:** 5.704E-7 mg/L $0.0022 \,\mu g/L$ 0.259 Agricultural Soil **Local PEC:** 1.499E-6 mg/kg dw 0.21 mg/kg < 0.01 STP **Local PEC:** 4.648E-9 mg/L 0.19 mg/L < 0.01

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Scaling method - Environment
Algorithm
Scalable parameters - Environment
Daily use. Local release rate
Boundaries of scaling -Environment
Do not exceed local release rate

ABBREVIATIONS		
BW	Body weight	
CS	Contributing Scenario	
DNEL	Derived no-effect level	
DU	Downstream user	
DW	Dry Weight	
ERC	Environmental release category	
ES	Exposure scenario	
PEC	Predicted Exposure Concentrations	
PNEC	Predicted no-effect concentration	
PROC	Process category	
RCR	Risk characterisation ratio	
STP	Sewage treatment plant	
TRA	Targeted Risk Assessment	