FICHA DE DATOS DE SEGURIDAD
(de acuerdo con el Reglamento (UE) 2020/878)

Establilizador cloro

SECCIÓN 1: IDENTIFICACIÓN DE LA SUSTANCIA O LA MEZCLA Y DE LA SOCIEDAD O LA EMPRESA.

1.1 Identificador de producto.

Nombre del producto:	Establilizador cloro
Nombre químico:	Ácido isocianúrico
N. CAS:	108-80-5
N. registro:	01-2119480421-45-XXXX

1.2 Usos pertinentes identificados de la sustancia o de la mezcla y usos desaconsejados.

Estabilizante de cloro

Usos desaconsejados:
Usos distintos a los aconsejados.

1.3 Datos del proveedor de la ficha de datos de seguridad.

Empresa:	**FLUIDRA COMMERCIAL, S.A.U.**
Dirección:	Av. Alcalde Barnils, 69
Población:	08174 Sant Cugat del Vallès (Barcelona) Spain
Provincia:	Barcelona
Teléfono:	Tel:34 93 724 39 00 Fax:34 93 724 29 93
Fax:	+34 93 713 41 11
E-mail:	fds@inquide.com
Web:	www.astralpool.com

1.4 Teléfono de emergencia: +34 93 724 39 00 (Sólo disponible en horario de oficina; Lunes-Viernes; 08:00-18:00)
Servicio de Información Toxicológica (Instituto Nacional de Toxicología y Ciencias Forenses) Teléfono: +34 91 5620420.
Información en español (24h/365 días). Únicamente con la finalidad de proporcionar respuesta sanitaria en caso de urgencia.

SECCIÓN 2: IDENTIFICACIÓN DE LOS PELIGROS.

2.1 Clasificación de la sustancia o de la mezcla.
El producto no está clasificado como peligroso según el Reglamento (EU) No 1272/2008.

2.2 Elementos de la etiqueta.
Consejos de prudencia:

P101	Si se necesita consejo médico, tener a mano el envase o la etiqueta.
P102	Mantener fuera del alcance de los niños.
P103	Leer atentamente y seguir todas las instrucciones.

2.3 Otros peligros.

La sustancia no es PBT
La sustancia no es mPmB
La sustancia no tiene propiedades de alteración endocrina.

En condiciones de uso normal y en su forma original, el producto no tiene ningún otro efecto negativo para la salud y el medio ambiente.

SECCIÓN 3: COMPOSICIÓN/INFORMACIÓN SOBRE LOS COMPONENTES.

3.1 Sustancias.

Identificadores	Nombre	Concentración	(*)Clasificación - Reglamento 1272/2008	
			Clasificación	Límites de concentración específicos y Estimación de Toxicidad Aguda

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N. CAS: 108-80-5	Ácido isocianúrico	80 - 100 %	-	-

3.2 Mezclas.
No Aplicable.

SECCIÓN 4: PRIMEROS AUXILIOS.

La información de la composición actualizada del producto ha sido remitida al Servicio de información Toxicológica (Instituto Nacional de Toxicología y Ciencias Forenses). En caso de intoxicación llamar al Servicio de Información Toxicológica:
Tfno (24 horas) 91 562 04 20
4.1 Descripción de los primeros auxilios.
Debido a la composición y a la tipología de las sustancias presentes en el preparado, no se necesitan advertencias particulares.

Inhalación.
Si se para la respiración aplicar respiración artificial y solicitar atención médica urgente. Situar al accidentado al aire libre, mantenerle caliente y en reposo, si la respiración es irregular o se detiene, practicar respiración artificial.

Contacto con los ojos.
Retirar las lentes de contacto, si lleva y resulta fácil de hacer. Lavar abundantemente los ojos con agua limpia y fresca durante, por lo menos, 10 minutos, tirando hacia arriba de los párpados y buscar asistencia médica. No permita que la persona se frote el ojo afectado.

Contacto con la piel.
Quitar la ropa contaminada.

Ingestión.
Mantenerle en reposo. NUNCA provocar el vómito.

4.2 Principales síntomas y efectos, agudos y retardados.
No se conocen efectos agudos o retardados derivados de la exposición al producto.

4.3 Indicación de toda atención médica y de los tratamientos especiales que deban dispensarse inmediatamente.
En los casos de duda, o cuando persistan los síntomas de malestar, solicitar atención médica. No administrar nunca nada por vía oral a personas que se encuentren inconscientes.

SECCIÓN 5: MEDIDAS DE LUCHA CONTRA INCENDIOS.

5.1 Medios de extinción.
Medios de extinción apropiados:
Polvo extintor o CO2. En caso de incendios más graves también espuma resistente al alcohol y agua pulverizada.

Medios de extinción no apropiados:
No usar para la extinción chorro directo de agua. En presencia de tensión eléctrica no es aceptable utilizar agua o espuma como medio de extinción.

5.2 Peligros específicos derivados de la sustancia o la mezcla.
Riesgos especiales.
La exposición a los productos de combustión o descomposición puede ser perjudicial para la salud.

5.3 Recomendaciones para el personal de lucha contra incendios.
Refrigerar con agua los tanques, cisternas o recipientes próximos a la fuente de calor o fuego. Tener en cuenta la dirección del viento.

Equipo de protección contra incendios.
Según la magnitud del incendio, puede ser necesario el uso de trajes de protección contra el calor, equipo respiratorio autónomo, guantes, gafas protectoras o máscaras faciales y botas.

SECCIÓN 6: MEDIDAS EN CASO DE VERTIDO ACCIDENTAL.

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6.1 Precauciones personales, equipo de protección y procedimientos de emergencia.
Para control de exposición y medidas de protección individual, ver sección 8.

6.2 Precauciones relativas al medio ambiente.
Producto no clasificado como peligroso para el medio ambiente, evitar en la medida de lo posible cualquier vertido.

6.3 Métodos y material de contención y de limpieza.
Contener y recoger el vertido con material absorbente inerte (tierra, arena, vermiculita, tierra de diatomeas...) y limpiar la zona inmediatamente con un descontaminante adecuado.
Depositar los residuos en envases cerrados y adecuados para su eliminación, de conformidad con las normativas locales y nacionales (ver sección 13).

6.4 Referencia a otras secciones.
Para control de exposición y medidas de protección individual, ver sección 8.
Para la eliminación de los residuos, seguir las recomendaciones de la sección 13.

SECCIÓN 7: MANIPULACIÓN Y ALMACENAMIENTO.

7.1 Precauciones para una manipulación segura.
El producto no requiere medidas especiales de manipulación, se recomiendan las siguientes medidas generales:
Para la protección personal, ver sección 8.
En la zona de aplicación debe estar prohibido fumar, comer y beber.
Cumplir con la legislación sobre seguridad e higiene en el trabajo.
No emplear nunca presión para vaciar los envases, no son recipientes resistentes a la presión. Conservar el producto en envases de un material idéntico al original.

7.2 Condiciones de almacenamiento seguro, incluidas posibles incompatibilidades.
El producto no requiere medidas especiales de almacenamiento.
Como condiciones generales de almacenamiento se deben evitar fuentes de calor, radiaciones, electricidad y el contacto con alimentos.
Mantener lejos de agentes oxidantes y de materiales fuertemente ácidos o alcalinos.
Almacenar los envases entre 5 y 35 ºC, en un lugar seco y bien ventilado.
Almacenar según la legislación local. Observar las indicaciones de la etiqueta. Una vez abiertos los envases, han de volverse a cerrar cuidadosamente y colocarlos verticalmente para evitar derrames.

El producto no se encuentra afectado por la Directiva 2012/18/UE (SEVESO III).

7.3 Usos específicos finales.
Ningún uso particular.

SECCIÓN 8: CONTROLES DE EXPOSICIÓN/PROTECCIÓN INDIVIDUAL.

8.1 Parámetros de control.

El producto NO contiene sustancias con Valores Límite Ambientales de Exposición Profesional.El producto NO contiene sustancias con Valores Límite Biológicos.

8.2 Controles de la exposición.

Medidas de orden técnico:

Concentración:	**100 %**
Usos:	**Estabilizante de cloro**
Protección respiratoria:	
Si se cumplen las medidas técnicas recomendadas no es necesario ningún equipo de protección individual.	
Protección de las manos:	
Si el producto se manipula correctamente no es necesario ningún equipo de protección individual.	
Protección de los ojos:	
Si el producto se manipula correctamente no es necesario ningún equipo de protección individual.	
Protección de la piel:	
EPI:	Calzado de trabajo
Características:	Marcado «CE» Categoría II.

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Normas CEN:	EN ISO 13287, EN 20347
Mantenimiento:	Estos artículos se adaptan a la forma del pie del primer usuario. Por este motivo, al igual que por cuestiones de higiene, debe evitarse su reutilización por otra persona.
Observaciones:	El calzado de trabajo para uso profesional es el que incorpora elementos de protección destinados a proteger al usuario de las lesiones que pudieran provocar los accidentes, se debe revisar los trabajor para los cuales es apto este calzado.

SECCIÓN 9: PROPIEDADES FÍSICAS Y QUÍMICAS.

9.1 Información sobre propiedades físicas y químicas básicas.
Estado físico: Sólido - Polvo
Color: Blanco
Olor: Inodoro
Umbral olfativo: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Punto de fusión: > 360 ºC
Punto de congelación: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Punto/Punto inicial/intervalo de ebullición: >300 ºC
Inflamabilidad: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Límite inferior de explosión: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Límite superior de explosión: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Punto de inflamación: 433 ºC (Estimación en base a las indicaciones del Reglamento (CE) Nº1272/2008)
Temperatura de auto-inflamación: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Temperatura de descomposición: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
pH: 2,1 - 3 (20 ºC)
Viscosidad cinemática: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Solubilidad: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Hidrosolubilidad: 2000 mg/l (25ºC)
Liposolubilidad: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Coeficiente de reparto (n-octanol/agua)(valor logaritmico): - 1.31 (25ºC)
Presión de vapor: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Densidad absoluta: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Densidad relativa: 1.75
Densidad de vapor: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Características de las partículas: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.

9.2 Otros datos.
Viscosidad: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Propiedades explosivas: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Propiedades comburentes: No
Punto de gota: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
Centelleo: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.
% Sólidos: No aplicable/No disponible debido a la naturaleza/las propiedades del producto.

SECCIÓN 10: ESTABILIDAD Y REACTIVIDAD.

10.1 Reactividad.
El producto no presenta peligros debido a su reactividad.

10.2 Estabilidad química.
Inestable en contacto con:
- Bases.

10.3 Posibilidad de reacciones peligrosas.
Puede producirse una neutralización en contacto con bases.

10.4 Condiciones que deben evitarse.
- Evitar el contacto con bases.

10.5 Materiales incompatibles.
Evitar los siguientes materiales:
- Bases.

-Continúa en la página siguiente.-

10.6 Productos de descomposición peligrosos.
Dependiendo de las condiciones de uso, pueden generarse los siguientes productos:
- Vapores o gases corrosivos.

SECCIÓN 11: INFORMACIÓN TOXICOLÓGICA.

11.1 Información sobre las clases de peligro definidas en el Reglamento (CE) nº 1272/2008.

Información Toxicológica.

Nombre	Toxicidad aguda			
	Tipo	Ensayo	Especie	Valor
Ácido isocianúrico N. CAS: 108-80-5 N. CE:	Oral	LD50	Rata	> 5000 mg/kg
	Cutánea	LD50	Rata	> 5000 mg/kg
	Inhalación	LC50	Rata	> 5.25 mg/l

a) toxicidad aguda;
Datos no concluyentes para la clasificación.

b) corrosión o irritación cutáneas;
Datos no concluyentes para la clasificación.

c) lesiones oculares graves o irritación ocular;
Datos no concluyentes para la clasificación.

d) sensibilización respiratoria o cutánea;
Datos no concluyentes para la clasificación.

e) mutagenicidad en células germinales;
Datos no concluyentes para la clasificación.

f) carcinogenicidad;
Datos no concluyentes para la clasificación.

g) toxicidad para la reproducción;
Datos no concluyentes para la clasificación.

h) toxicidad específica en determinados órganos (STOT) - exposición única;
Datos no concluyentes para la clasificación.

i) toxicidad específica en determinados órganos (STOT) - exposición repetida;
Datos no concluyentes para la clasificación.

j) peligro por aspiración;
Datos no concluyentes para la clasificación.

11.2 Información relativa a otros peligros.

Propiedades de alteración endocrina.
Este producto no contiene componentes con propiedades de alteración endocrina con efectos sobre la salud humana.
Otros datos.
No existe información disponible sobre otros efectos adversos para la salud.

SECCIÓN 12: INFORMACIÓN ECOLÓGICA.

12.1 Toxicidad.

Nombre	Ecotoxicidad			
	Tipo	Ensayo	Especie	Valor

-Continúa en la página siguiente.-

Ácido isocianúrico N. CAS: 108-80-5 N. CE:	Peces	LC50	Pez	2100 mg/l (96 h)
	Invertebrados acuáticos			
	Plantas acuáticas	EC50	Algas	3780 mg/l (96 h)

12.2 Persistencia y degradabilidad.
No se dispone de información relativa a la biodegradabilidad.
No se dispone de información relativa a la degradabilidad.
No existe información disponible sobre la persistencia y degradabilidad del producto.

12.3 Potencial de bioacumulación.
Información sobre la bioacumulación.

Nombre	Bioacumulación			
	Log Kow	BCF	NOECs	Nivel
Ácido isocianúrico N. CAS: 108-80-5 N. CE:	- 1.31 (25ºC)	-	-	Muy bajo

12.4 Movilidad en el suelo.
No existe información disponible sobre la movilidad en el suelo.
No se debe permitir que el producto pase a las alcantarillas o a cursos de agua.
Evitar la penetración en el terreno.

12.5 Resultados de la valoración PBT y mPmB.
No existe información disponible sobre la valoración PBT y mPmB del producto.

12.6 Propiedades de alteración endocrina.
Este producto no contiene componentes con propiedades de alteración endocrina sobre el medio ambiente.

12.7 Otros efectos adversos.
No existe información disponible sobre otros efectos adversos para el medio ambiente.

SECCIÓN 13: CONSIDERACIONES RELATIVAS A LA ELIMINACIÓN.

13.1 Métodos para el tratamiento de residuos.
No se permite su vertido en alcantarillas o cursos de agua. Los residuos y envases vacíos deben manipularse y eliminarse de acuerdo con las legislaciones local/nacional vigentes.
Seguir las disposiciones de la Directiva 2008/98/CE respecto a la gestión de residuos.

SECCIÓN 14: INFORMACIÓN RELATIVA AL TRANSPORTE.

No es peligroso en el transporte. En caso de accidente y vertido del producto actuar según el punto 6.

14.1 Número ONU o número ID.

-Continúa en la página siguiente.-

No es peligroso en el transporte.

14.2 Designación oficial de transporte de las Naciones Unidas.
Descripción:
ADR/RID: No es peligroso en el transporte.
IMDG: No es peligroso en el transporte.
ICAO/IATA: No es peligroso en el transporte.

14.3 Clase(s) de peligro para el transporte.
No es peligroso en el transporte.

14.4 Grupo de embalaje.
No es peligroso en el transporte.

14.5 Peligros para el medio ambiente.
No es peligroso en el transporte.
Transporte por barco, FEm - Fichas de emergencia (F – Incendio, S – Derrames): No aplicable.

14.6 Precauciones particulares para los usuarios.
No es peligroso en el transporte.

14.7 Transporte marítimo a granel con arreglo a los instrumentos de la OMI.
No es peligroso en el transporte.

SECCIÓN 15: INFORMACIÓN REGLAMENTARIA.

15.1 Reglamentación y legislación en materia de seguridad, salud y medio ambiente específicas para la sustancia o la mezcla.
El producto no está afectado por el Reglamento (CE) nº 1005/2009 del Parlamento Europeo y del Consejo, de 16 de septiembre de 2009, sobre las sustancias que agotan la capa de ozono.

Clasificación del producto de acuerdo con el Anexo I de la Directiva 2012/18/UE (SEVESO III): N/A

El producto no está afectado por el Reglamento (UE) No 528/2012 relativo a la comercialización y el uso de los biocidas.
El producto no se encuentra afectado por el procedimiento establecido en el Reglamento (UE) No 649/2012, relativo a la exportación e importación de productos químicos peligrosos.

Clase de contaminante para el agua (Alemania): nwg: No peligroso para el agua (Autoclasificado según Reglamento AwSV)

15.2 Evaluación de la seguridad química.
No se ha llevado a cabo una evaluación de la seguridad química del producto.
Se dispone de Escenario de Exposición del producto.

SECCIÓN 16: OTRA INFORMACIÓN.

Modificaciones respecto a la versión anterior:

- Anexados los escenarios de exposición (SECCIÓN 15.2).

Clasificación y procedimiento utilizado para determinar la clasificación de las mezclas con arreglo al Reglamento (CE) nº 1272/2008 [CLP]:

Peligros físicos	Conforme a datos obtenidos de los ensayos
Peligros para la salud	Método de cálculo
Peligros para el medio ambiente	Método de cálculo

Se recomienda utilizar el producto únicamente para los usos contemplados.

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Se dispone de Escenario de Exposición del producto.

Abreviaturas y acrónimos utilizados:
AwSV: Reglamento de Instalaciones para la manipulación de sustancias peligrosas para el agua.
BCF: Factor de bioconcentración.
CEN: Comité Europeo de Normalización.
EC50: Concentración efectiva media.
EPI: Equipo de protección personal.
LC50: Concentración Letal, 50%.
LD50: Dosis Letal, 50%.
NOEC: Concentración sin efecto observado.
WGK: Clases de peligros para el agua.

Principales referencias bibliográficas y fuentes de datos:
http://eur-lex.europa.eu/homepage.html
http://echa.europa.eu/
Reglamento (UE) 2020/878.
Reglamento (CE) No 1907/2006.
Reglamento (EU) No 1272/2008.

La información facilitada en esta ficha de Datos de Seguridad ha sido redactada de acuerdo con el REGLAMENTO (UE) 2020/878 DE LA COMISIÓN de 18 de junio de 2020 por el que se modifica el anexo II del Reglamento (CE) n.o 1907/2006 del Parlamento Europeo y del Consejo, relativo al registro, la evaluación, la autorización y la restricción de las sustancias y mezclas químicas (REACH).

La información de esta Ficha de Datos de Seguridad del Producto está basada en los conocimientos actuales y en las leyes vigentes de la CE y nacionales, en cuanto que las condiciones de trabajo de los usuarios están fuera de nuestro conocimiento y control. El producto no debe utilizarse para fines distintos a aquellos que se especifican, sin tener primero una instrucción por escrito, de su manejo. Es siempre responsabilidad del usuario tomar las medidas oportunas con el fin de cumplir con las exigencias establecidas en las legislaciones.

-Fin de la ficha de datos de seguridad.-

1.1 Identified uses

Table 1. Description of identified uses

Identified use	**Sector of Use (SoU)**	**Preparation Category (PC)**	**Process category (PROC)**	**Article category (AC)**	**Environmental Release Category (ERC)**
Intermediate	SU 8	PC 19	PROC 1 PROC 4 PROC 5	NA	ERC 1 ERC 2:
Stabilizer for swimming pool disinfection	SU 21	PC 37	PROC 8 PROC 9 PROC 14	NA	ERC 1 ERC 2
Plastic formulation ingredient	SU 12	PC 32	PROC 6 PROC 14	NA	ERC 2

1.2 Uses advised against

Currently there are no uses of CYA which are advised against.

2 HUMAN HEALTH HAZARD ASSESSMENT

2.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

2.1.1 Non-human information

Table 2. Toxicokinetics, metabolism and distribution

Radiochemical	Route	Species, strain, sex, No./Group	Dose level, mg/kg bw Holding period	Recovery (%) Total	Urine	Faeces	CO_2	Retained dose (%)	Reference
^{14}C-sodium cyanurate monohydrate (77.5% cyanuric acid)	i.v. oral oral oral	Rat, Sprague-Dawley, 5 /sex/dose/group CO_2 collection group: 2 /sex/dose 15 day dose (no kinetics or peak blood conc. monitoring)	5 5 500 5, radiolabelled only on 15th day	100%	>95% >95% 30% males /45% females >95%	< 5% < 5% 70% males /55% females < 5%	trace	not detectable	Chadwick MD, Hayes D, Branfman AR, McComish MF, Macauley JB, Mazrimas MJ (1982)
^{14}C-sodium cyanurate monohydrate (77.5% cyanuric acid)	i.v. oral oral oral	Dog, Beagle, 4 /sex/group, 15 day with 2 /sex/dose	5 5 500 5 for 14 days and radiolabelled on 15th day, except one female with 4.5 radiolabelled	81-101%	>98% >98% 14-73% remainder	< 2% < 2% remainder 6-13%		not detectable	Chadwick M, Hayes D, McComish MF, Macauley JB, Mazrimas MJ (1982)
^{14}C-cyanuric acid	oral	Rat, Wistar, male, 3/group	Single dose: 50 µCi/0.410 mg/mL/kg 0.25 h 0.5 h 1 h 3 h 6 h 12 h	 -- -- -- 70% 88% 90%	 0% 9% 19% 63% 87% 89%	 0% 0% < 1% < 1% < 1% 1%	 NR	Stomach and intestines: 60% 20% 20% 7% 1% < 1%	Inokuchi N, et al (1978)

Table 3. Dermal absorption (animal data)

Radiochemical	Species, strain, sex, No./Group	Dose level, mg/kg bw, Holding period	Recovery Total	Urine	Blood	Skin	Washings	Reference

Radiochemical	Species, strain, sex, No./Group	Dose level, mg/kg bw, Holding period	Recovery					Reference
			Total	Urine	Blood	Skin	Washings	
^{14}C-cyanuric acid	Rat, Sprague-Dawley Guinea-pig Human abdominal skin Testskin®	1 µCi or 100 µCi ^{14}C-CYA 55 mg/l CYA :1.5 mg/l chlorine : 100 ml water 24 hours	Human skin = 0.2 mg/day absorbed Rat: max permeation = 0.06 µg/cm^2/h Guinea-pig: max permeation = 0.01 µg/cm^2/h			Human: 0% Rat: max 0.05% Guinea-pig: max 0.17%	Human: 0% Rat: max 0.23% Guinea-pig: 0%	Moody RP et al (1993)
^{14}C-cyanuric acid	Rat, Wistar, male, 3/group	0.0021 mg/kg bw 6 h application 9 h application 12 h application	 87.54% 84.74% 86.73%	 0.008% 0.007% 0.009%	 Not detected Not detected Not detected	 2.24% 2.71% 1.24%	 85.29% 82.02% 85.48%	Inokuchi N, et al (1978)

2.1.2 Human information

Table 4. Oral (human data)

Radiochemical	Route	Species, strain, sex, No./Group	Dose level, mg/kg bw, Holding period	Recovery (%)		Reference
				Total	Urine	
Cyanuric acid	oral	Human 2	21.4 mg	100%	100%	Duncan RC (1980)
Cyanuric acid	oral	Human Children (6 - 17 years): 20 males/21 females Adults: 4 male/8 female	Dosage variable – normal exposure rate from swimming pool water maintained at 30 – 50 mg/l CYA 45 minutes		> 98%	Dufour AP et al (2006)

Table 5. Dermal absorption (human data)

Radiochemical	Species, strain, sex, No./Group	Dose level, mg/kg bw, Holding period	Recovery (urine)	Reference
Cyanuric acid	Human			Duncan RC (1980)

Radiochemical	Species, strain, sex, No./Group	Dose level, mg/kg bw, Holding period	Recovery (urine)	Reference
	Swimming trial: 55 male/female (9-19 years) 11 male/female (9-37 years) Dermal study: 4 males	30 mg/l Control: 1 mg/l 30 mg/l (1 hour)	90% 0.25 mg/h	
Cyanuric acid	Human 1 male, 4 female 9 – 17 years	Dosage variable – normal exposure rate from swimming pool water. 120 min	0.03 – 2.8 mg	Allen L et al (1982)

2.1.3 Summary and discussion on toxicokinetics

Cyanuric acid (CYA) is a weak acid, with three ionizable protons. In aqueous solution, the dissociation of CYA is described by the three dissociation constants pKa1, pKa2 and pKa3 given in Table 4. At neutral pH (7.0) about 43% of the cyanuric acid in solution is present as cyanuric acid and 57% is present as the cyanurate ion. Thus, toxicity data for cyanuric acid or sodium cyanurate are equivalent, when expressed on a CYA basis.

Studies have been conducted on the absorption, distribution, metabolism and excretion of radiolabelled sodium cyanurate (equivalent to 77.5% CYA) after single i.v. and repeated oral administration. No metabolism or accumulation was demonstrated in either of the two animal studies in dogs and rats with 100% of the radioactive label recovered in urine and faeces. Over 98% of the cyanuric acid was absorbed from the GI tract. The findings of the animal studies are upheld in a pilot study in humans ingesting swimming pool water where > 98% of a measured dose of CYA was recovered in urine within 24 hours of dosing (Dufour et al 2006). In oral ingestion studies in 2 volunteers, total recovery of cyanuric acid was 21 and 21.2 mg and interpolated 90% excretion was at 3.1 or 3.5 h ($t_{1/2}$ ~ 1 h). The volunteers ingested 100 ml of water containing 214 ppm cyanurate (or 21.4 mg cyanurate) thus essentially 100% was recovered in the urine.

In dermal absorption studies where human skin was tested with a pool concentration of unlabelled cyanuric acid and chlorine, only 0.06 μg/cm^2 total cumulative absorption was detected over the 24 h exposure period (Moody et al 1993). Employing a value of 1.83 m^2 for the total body surface area of a 70 kg human, would imply an exposure of 1.1 mg for a 24 h exposure period. Assuming a worse case maximum exposure time of 5 h daily the data suggests that 0.2 mg/day would be absorbed through a swimmers skin. For a standard water cyanuric acid concentration of 55 ppm, 0.2 g of cyanuric acid would be contained in 3.6 mL pool water. Therefore exposure by the oral route could easily supersede that of dermal.

2.2 Acute toxicity

2.2.1 Acute toxicity: oral

Table 6. Acute oral toxicity

Route	Test material	Method, Guideline	Species, strain, sex, No./Group	Dose levels, Duration of exposure	Values LD50/LC50	References
Oral	Crude CYA*	Comparable to OECD 401	rat, Sprague-Dawley, 5 /sex	5000 mg/kg bw	> 5000 mg/kg bw	Branch DK (1981)

* Crude CYA = contains ~80% CYA, ~15% ammelide, ~4% ammelide, remainder = melamine, urea and biuret

2.2.2 Acute toxicity: dermal

Table 7. Acute oral toxicity

Route	Test material	Method, Guideline	Species, strain, sex, No./Group	Dose levels, Duration of exposure	Values LD50/LC50	References
Dermal	Crude CYA	Comparable to OECD 402	rabbit, New Zealand white, 5 /sex	5000 mg/kg bw, 24 hr	> 5000 mg/kg bw	Branch DK (1981)

2.2.3 Acute toxicity: inhalation

Table 8. Acute inhalation toxicity

Route	Test material	Method, Guideline	Species, strain, sex, No./Group	Dose levels, Duration of exposure	Values LD50/LC50	References
Inhalation	CYA	OECD 403	rats, Sprague Dawley 5 /sex	5.25 mg/L 4 hr	> 5.25 mg/L	Younger N (2009)

2.2.4 Summary and discussion of acute toxicity

Acute oral and dermal studies were performed in male and female rats with Crude CYA (Branch 1981). No mortalities were observed in either sex at 5000 mg/kg following oral administration. No mortalities were observed following dermal application of 5000 mg/kg to the shaved and abraded dorsal surface of albino rabbits of both sexes. An acute inhalation study (nose only exposure) with CYA gave an LC50 > 5.25 mg/L. CYA is not classified for acute oral, dermal or inhalation exposure.

2.3 Irritation

2.3.1 Skin

Table 9. Skin irritation

Species	Test material	Method	Average score 24, 48, 72 h		Reversibility (yes/no)	Result	References
			Erythema	Oedema			
Rabbit	Crude CYA	Comparable to US FIFRA (intact and abraded skin)	0	0	Not applicable	Not irritating	Branch DK (1981)

2.3.2 Eye

Table 10. Eye irritation

Species	Test material	Method	Average score 24, 48, 72 h			Result	Reversibility (yes/no)	References
			Cornea opacity	Iris inflammation	Conjunctiva redness			
Rabbit	Crude CYA	Not stated	0.0, 0.0, 0.0	0.0, 0.0, 0.0	0.7, 0.3, 0.0	Not irritating	Yes	Branch DK (1981)

2.3.3 Respiratory tract

No data

2.3.4 Summary and discussion of irritation

Skin irritation

In an *in vivo* skin irritation study (Branch 1990) 500 mg cyanuric acid was applied to the abraded skin of 6 New Zealand White rabbits under an occlusive patch for 24 hours. Animals were observed after removal of the patch up to 72 h. The average of the erythema and edema assessments for the 6 animals after 72 h was 0.0. Calcium sulfate was found to be non-irritating to the skin in rabbits.

Eye irritation

In an *in vivo* eye irritation study (Branch 1981) 82 mg cyanuric acid was instilled into the eyes of 6 New Zealand White rabbits. Ocular observations were made at 24, 48 and 72 h after instillation. The average of the Draize scores for 24, 48 and 72 h was 0.3. All irritation had subsided by 72 h after exposure. No corneal or iridal involvement was observed. Cyanuric acid is not irritating to eyes.

2.4 Corrosivity

No signs of corrosivity were observed in the irritation studies. CYA is not corrosive.

2.5 Sensitisation

2.5.1 Skin

Table 11. Skin sensitisation – Local Lymph Node Assay

Species	Method	Stimulation index (SI)			Result	References
		25%	50%	100%		
Mouse	Local lymph node assay	2.1	3.4	3.7	Weak sensitizer*	Kuhn JO (2008)

	(LLNA) OECD 429					

* Refer to section 5.5.3 for additional discussion

2.5.1.1 Human information

Though no human studies are available for CYA information from historical use is available. No known incidents or complaints of skin sensitisation were recalled from workers handling CYA in manufacture or application of the product. No known incidents or complaints of post application exposure to swimmers attributed specifically to CYA in swimming pools were recalled. The maximum recommended CYA levels in swimming pools are typically 100 ppm (WHO Guidelines For Safe Recreational Water Environments, 2000) or less which is well below the levels tested in the LLNA study 25% (250 000 ppm) which did not elicit a positive response.

2.5.2 Respiratory system

No data

2.5.3 Summary and discussion of sensitisation

The results of the LLNA study (Kuhn JO 2008) indicated that CYA elicited a positive response for potential skin sensitization, based on test/vehicle control ratio or stimulation index (SI) of 3 or greater in two of the three concentrations tested (50% and 100%). These positive results were considered indicators of borderline or mild skin sensitization potential. The test group at 25% CYA was below the SI of 3 threshold for a positive response. The severity of response was low, just above the SI threshold of 3 for only two of the three concentrations tested, which were considered borderline positive. In addition, the response at 25% CYA was below this threshold and not considered a positive response. On this basis CYA should not be classified as a skin sensitizer.

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2.6 Repeated dose toxicity

2.6.1 Repeated dose toxicity: oral

Table 12. Repeat dose drinking water studies

Route	Test substance	Duration of study	Species, strain, sex, no./group	Dose levels, frequency of application	Results	LO(A)EL	NO(A)EL	References
drinking water	monosodium cyanurate monohydrate (CYA 77.34%)	28 days extended to 59 days	Rat, CD, 5 /sex/dose (10/sex control)	400, 1200, 2000, 4000 mg/l ad libitum (males: 48.8, 141.4, 260.1, 520.7 mg/kg bw/d; females: 64.5, 264.2, 370.4, 717.0 mg/kg bw/d)	No dose related indications of toxicity observed.	> 4000 ppm (males 521 mg/kg bw/d; females 717 mg/kg bw/d)	ca. 4000 mg/l (males 521 mg/kg bw/d; females 717 mg/kg bw/d)	Biava C (1980)
drinking water	monosodium cyanurate monohydrate (CYA 77.34%)	90 days	Rat, CD, 40/sex/dose except 896 & 1792 with 24 /sex/dose	0, 896, 1792, 5375 mg/l, ad libitum (based on total s-triazinetriol content	No mortalities. Hyperplasia of urinary bladder epithelium of males. NOAEL based on observation of slight hyperplasia in one male at the mid-dose level.	1792 mg/l (males = 231mg/kg bw/day)	896 mg/l (males = 109 mg/kg bw/day)	Rajasekaran D (1981)
drinking water	monosodium cyanurate monohydrate (CYA 77.4%)	104 weeks	Rat, CD, Control:100 /sex 400 ppm: 80/sex other doses: 100/sex/dose	0, 400, 1200, 2400, 5375 ppm	Some males were more susceptible during the early stages of the study to substance related effects than females. High: heart and urinary tract lesions in males during first 12 months.	5375 ppm (males = 371 mg/kg bw/day, females = 634 mg/kg bw/day)	2400 ppm (males = 154 mg/kg bw/day, females = 266 mg/kg bw/day)	Blair M (1985)
drinking water	monosodium cyanurate monohydrate (CYA 77.5%)	104 weeks	mice, $B_6C_3F_1$ Control:100 /sex 100 ppm: 80/sex other doses: 100/sex/dose	0, 100, 400, 1200, 5375 ppm	No significant toxicological effects noted.	> 5375 ppm (males = 1523 mg/kg bw/day, females = 1582 mg/kg bw/day)	5375 ppm (males = 1523 mg/kg bw/day, females = 1582 mg/kg bw/day)	Serota DG (1986)

2.6.2 Summary and discussion of repeated dose toxicity

Subchronic and chronic drinking water studies were performed with monosodium cyanurate (77.34 - 77.5% CYA) and concentrations corrected accordingly. For CYA, the NOAEL for sub-chronic effects (90-days) is 109 mg/kg bw/day for males based on hyperplasia in the urinary bladder observed in one male in the mid-dose group (Rajasekaran D 1981) The hyperplasia in males observed in the sub-chronic study has been elucidated in the 2-year combined chronic toxicity and cytogenicity study (Blair M 1985) where it was seen that male rats were more susceptible to dose related effects during the early stages of the study with reversal of effects over the full dosing period. The No Observed Effect Level (NOEL) in males was identified as 154 mg/kg bw/day and the Lowest Observed Adverse Effect Level in the male was 371 mg/kg bw/day). The low sub-chronic NOAEL (109 mg/kg bw/day, male) should be considered as redundant based on the findings of the 2-year chronic study. The NOEL for males of 154 mg/kg bw/day from the 2-year combined chronic toxicity/carcinogenicity study is applicable for risk characterisation as a precautionary approach.

2.7 Mutagenicity

2.7.1 In vitro data

Table 13. In vitro genotoxicity

Test system, Method guideline	Test substance	Organism/ strain(s)	Concentrations tested	Result		References
				+S9	-S9	
Ames Test, Comparable to OECD 471	monosodium cyanurate monohydrate (CYA 77.34%)	*Salmonella typhimurium*: TA98, TA100, TA1535, TA1537	0.01, 0.04, 0.2, 1, 3, 10 mg/plate	-ve	-ve	Gridley J, Ross WD (1980)
Mouse lymphoma assay, Comparable to OECD 476	monosodium cyanurate monohydrate (CYA 77.34%)	L5178Y TK+/- mouse lymphoma cells	+S9: 250, 500, 750, 1000, 1250, 1500, 1750, 2000; -S9: 50, 100, 250, 500, 750, 1000, 1250, 1500, 1750, 2000 µg/ml	-ve	-ve	Kirby PE (1981)
Sister chromatid exchange assay, Comparable to OECD 479	monosodium cyanurate monohydrate (CYA 77.34%)	Chinese hamster ovary cells, ATCC CCL 61, CHO-K1	93.8, 187.5, 375, 750, 1500 µg/ml	-ve	-ve	Stewart BE (1981)

2.7.2 In vivo data

Table 14. In vivo genotoxicity

Type of test Method/ Guideline	Test substance:	Species, strain, sex, no./group	Dose levels	Sampling times	Results	References
Mammalian Bone Marrow Chromosome Aberration Test. Comparable to OECD 475	monosodium cyanurate monohydrate (CYA 77.5%)	Rat, Sprague-Dawley, male, 10/dose	0, 1.25, 2.50, 5.0 g/kg bw	24 or 46 hours	-ve	Sharma RK (1981)

2.7.3 Summary and discussion of mutagenicity

In vitro gene mutation study in bacteria:

Monosodium cyanurate monohydrate was tested in a bacterial reverse mutation assay (Gridley and Ross 1980) in *S. typhimurium* strains TA100, TA1535, TA1537, TA97, TA98 and TA100 in a plate incorporation assay and spot test with and without metabolic activation (S9). Cyanuric acid was not mutagenic towards *Salmonella typhimurium*test strains in the plate incorporation or spot tests conducted with or without a rat microsomal activation system. No microbial toxicity was observed with or without microsomal activation.

In vitro gene mutation study in mammalian cells:

The sodium salt of cyanuric acid was tested for its abilty to induce mutations in mouse lymphoma L5178Y cells in the presence and absence of metabolic activation (Kirby 1981). The test susbtance did not induce any toxicologically significant increases in the mutant frequency at the TK +/- locus in L5178Y cells and was therefore considered to be non mutagenic under the conditions of the test.

In vitro cytogenicity study in mammalian cells

Monosodium cyanurate was tested in a sister chromatid exchange assay (Stewart 1981) in cultured Chinese hamster ovary (CHO) cells Without metabolic activation, CHO cells were exposed to five concentrations of monosodium cyanurate ranging from 93.8 to 1500 µg/mL. With metabolic activation, CHO cells were exposed to monosodium cyanurate at five concentrations ranging from 93.6 to 1500 µg/mL. Monosodium cyanurate did not induce SCEs in CHO cells with or without metabolic activation.

In vivo micronucleus assay:

In a reliable OECD guideline study (Sharma 1981) male mice were given 1.25, 2.50 and 5.00 g/kg bw doses of sodium cyanurate. No mutagenic effects were observed at 24 or 48 hours post dosing, in the bone marrow cells of male rats dosed orally with 1.25, 2.5, or 5.00 g/kg sodium cyanurate.

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2.8 Carcinogenicity

2.8.1 Carcinogenicity: oral

Table 15. Carcinogenicity in rat and mouse

Route	Test substance	Duration of study	Species, strain, sex, no./group	Dose levels, frequency of application	Tumours and non-neoplastic lesions	References
drinking water	monosodium cyanurate monohydrate (CYA 77.4%)	104 weeks	Rat, CD Control:100 /sex 400 ppm: 80/sex other doses: 100/sex/dose	0, 400, 1200, 2400, 5375 ppm ad libitum	Test substance related non-neoplastic lesions were only observed in the urinary tract in males from the 5375 mg/l group sacrificed at the 6 and 12 month interims.	Blair M (1985)
drinking water	monosodium cyanurate monohydrate (CYA 77.5%)	104 weeks	mice, $B_6C_3F_1$ Control:100 /sex 100 ppm: 80/sex other doses: 100/sex/dose	0, 100, 400, 1200, 5375 ppm, ad libitum	No definitive treatment-related effects were observed at any of the dose levels tested.	Serota DG (1986)

2.8.2 Summary and discussion of carcinogenicity

Two carcinogenicity drinking water studies with monosodium cyanurate monohydrate (77.4 - 77.5% CYA) were performed, one in the rat and the other in the mouse. In both studies there is no evidence of carcinogenic potential of the test material. The lowest NOEL derived was that in male rats 154 mg/kg bw/day (Blair M 1985) due to test substance related urinary tract lesions which occurred in the first half of the study. At the highest dose, the test substance precipitated in the urinary bladder. No treatment related effects were observed in the study performed with mice.

2.9 Toxicity for reproduction

2.9.1 Effects on fertility

Table 16. Two generation developmental toxicity

Route	Test substance	Test type Method Guideline	Species, strain, sex, no. /group	Exposure period	Doses	Critical effects	NO(A)EL parental	NO(A)EL F1	NO(A)EL F2	References
							m & f	m & f	m & f	
drinking water	sodium cyanurate monohydrate (CYA 77.05%)	2-generation. Comparable to OECD 416	Rat, CD, 12 male & 24 female /dose	103 weeks	0, 400, 1200, 5375 ppm	No consistent adverse effects to reproductive parameters or off-spring toxicity. Reduced NOAEL for F2 males is in relation to an increased incidence of calculi in the urinary bladder related to the test article.	5375 ppm (males = 470 mg/kg bw/day, females = 950 mg/kg bw/day)	5375 ppm (males = 500 mg/kg bw/day, females = 910 mg/kg bw/day)	1200 ppm Males (190 mg/kg bw/day) 5375 ppm, females (970 mg/kg bw/day)	Aldridge D et al. (1985)

2.9.2 Developmental toxicity

Table 17. Teratogenicity

Route	Test substance	Test type, Method Guideline	Species, strain, sex, no. /group	Exposure period	Doses	Critical effects, dams, fetuses	NO(A)EL maternal toxicity	NO(A)EL Teratogenicity embryotoxicity	References
gavage	monosodium cyanurate	Comparable to OECD 414	rabbit, New Zealand white, female 20/dose group	Days 6 to 18 of gestation	0, 20, 50, 200, 500 mg/kg bw/day	Dams: reduced bodyweight gains. No adverse effect on teratology or fetotoxicity.	> 500 mg/kg bw/day	≥500 mg/kg bw/day	Rodwell DE (1990)
gavage	monosodium cyanurate monohydrate (CYA 77.4%)	Comparable to OECD 414	rat, CD, female, 25 /dose group	Days 6 to 15 of gestation	200, 1000, 5000 mg/kg bw/day	No adverse effect on teratology or fetotoxicity.	> 5000 mg/kg bw/day	≥ 5000 mg/kg bw/day	Laughlin KA (1982)

2.9.3 Summary and discussion of reproductive toxicity

In a two generation rat study, the NO(A)EL for adult toxicity of the monosodium cyanurate is 5375 ppm corrected to CYA concentrations (males = 470 mg/kg bw/day, females 910 mg/kg/day) with the exception of F_2 males where the NOEL = 1200 ppm (190 mg/kg/day). This is based on the related incidence of calculi in the urinary bladders of high dose animals seen at the highest dose level. Effects on the urinary tract in male rats were also observed in the repeat oral dose toxicity studies. Monosodium cyanurate did not produce any consistent effects on reproductive parameters or offspring toxicity; therefore 5375 ppm (470 – 500 mg/kg bw/day for males and 910 – 970 mg/kg bw for females) is assessed as the NOEL for reproductive and offspring effects.

In the rabbit study, NO(A)EL maternal toxicity based on the statistical significance of the toxicological observations is 500 mg/kg bw/day. However, there was no evidence of developmental toxicity in any of the treated groups. Hence the NO(A)EL for developmental toxicity was assessed to be at least 500 mg/kg bw/day.

In the rat study, monosodium cyanurate did not produce a maternal toxicity or teratogenic response when administered by gavage at a dose of 5000 mg/kg bw/day or less.

2.10 Derivation of DNEL

2.10.1 Overview of typical dose descriptors for all endpoints

Table 18. Available dose descriptor(s) per endpoint for a certain substance as a result of its hazard assessment.

Endpoint		**Quantitative dose descriptor (appropriate unit) or qualitative assessment**		**Associated relevant effect**	**Remarks on study**
		Local	Systemic		
Acute toxicity	oral	LD50 >5000 mg/kg bw/day NOAEL(mat/ terat): >500 mg/kg/d	N/A	None observed	Acute oral in rats and oral teratology study in rabbits
	dermal	LD50 >5000 mg/kg bw/day	N/A	None observed	Acute dermal tox in rats
	inhalation	LC50 > 5.25 mg/L	N/A	None observed	Acute inhalation tox in rats
Irritation/Corrosivity	skin	N/A	NA	Not irritating	
	eye	N/A	NA	Not irritating	
Sensitisation	skin	Not sensitizing	NA	Not sensitizing	
Repeated dose toxicity sub-acute/ sub-chronic/ chronic	oral		NOEL 154 mg/kg bw/day*	High incidence of urinary bladder calculi observed in male rats and test article related heart and urinary tract lesions (first 12 months of study)	2-yr drinking water combined chronic toxicity/carcinogenicity study in rats
Mutagenicity	in vitro	Negative	N/A	Not mutagenic	
	in vivo	Negative	N/A	Not mutagenic	
Carcinogenicity	oral	Not carcinogenic		Not carcinogenic	
Reproductive toxicity fertility impairment	oral	NA			
Reproductive toxicity developmental tox	oral	NA			

*The NOEL value from the 2-year combined chronic toxicity/carcinogenicity study is applicable in the absence of a NOAEL value for systemic toxicity.

2.10.2 Correction of dose descriptors if needed (for example route-to-route extrapolation), application of assessment factors and derivation of the endpoint specific DN(M)EL

See section 5.10.3

2.10.3 Selection of the critical DNEL(s)/DMELs and/or qualitative/semi-quantitative descriptor for critical health effects

Table 19. :DNELs for workers

Exposure pattern	Route	Descriptors	DNEL/DMEL (appropriate unit)	Most sensitive endpoint
Acute - systemic effects	Dermal (mg/kg bw /day)	DNEL	3.08 mg/Kg (from chronic)	2 year repeat oral dose study
	Inhalation (mg/m^3)	DNEL	10.86 mg/m^3	2 year repeat oral dose study
Acute - local effects	Dermal (mg/cm^2)	N/A	N/A	
	Inhalation (mg/m^3)	N/A	N/A	
Long-term - systemic effects	Dermal (mg/kg bw /day)	DNEL	3.08 mg/Kg	2 year repeat oral dose study
	Inhalation (mg/m^3)	DNEL	10.86 mg/m³	2 year repeat oral dose study
Long-term – local effects	Dermal (mg/cm^2)	N/A	N/A	
	Inhalation (mg/m^3)	N/A	N/A	

Discussion – Derivation of DNELs for workers

Acute dermal local:
The acute dermal DNEL for local effects cannot be determined as irritation or corrosion data showing a dose response correlation is not available.

Acute inhalation local:
The acute inhalation DNEL for local effects couldn't be derived as the irritative potential of CYA on the respiratory tract was not tested

Acute dermal systemic:
The acute dermal DNEL for systemic effects is the same as that for long-term DNEL which is considered sufficient to ensure that these effects do not occur.

Acute inhalation systemic:
The acute inhalation DNEL for systemic effects is the same as that for the long term DNEL which is considered sufficient to ensure that these effects do not occur.

Long-term dermal systemic:
The long-term dermal DNEL for systemic effects is calculated based on a route to route extrapolation from a chronic oral drinking water study assuming complete absorption via the dermal route which is a very conservative assumption given the low dermal permeability (see chapter 5.1.3).
The starting value is the NOAEL (oral, rat chronic) of 154 mg/Kg.
The assessment factor is the product of:
- factor for route-to-route extrapolation: 1.0
- interspecies factor: 2.5
- allometric scaling: 4.0
- intra species factor for workers: 5
- total assessment factor (product of assessment factors): 50
- total factor (product of assessment factors x route-to-route factor): 50
- derived long-term dermal DNEL for systemic effects: 3.08 mg/Kg bw

Long-term inhalative systemic:
The long-term inhalation DNEL for systemic effects is calculated based on a route to route extrapolation from a chronic oral drinking water study.
The starting value is the NOAEL (oral, rat chronic) of 154 mg/Kg.
To convert this into a NAEC for workers the following calculation is applied:
154 mg/Kg /0.38 m^3/kg bw x 0.67m^3/10m^3 = 271.5 mg/m^3 (NAEC worker 8 h)

The assessment factor is the product of:
AF of 2.5 (default) for remaining interspecies differences.
AF of 5 is applied for intraspecies differences for workers
AF of 2 is applied for route to route extrapolation of oral to inhalation exposure
The total AF applied is obtained by multiplication of all the assessment factors (2.5 * 5 * 2) giving an overall assessment factor of 25.
The inhalation worker DNEL for systemic effects is 271.5/25 = 10.86 mg/m^3

Long-term dermal local:
The long-term dermal DNEL for local effects couldn't be derived as results from repeated dose experiments are not available for dermal toxicity.

Long-term inhalation local:
The long-term inhalation DNEL for local effects couldn't be derived as results from repeated dose experiments are not available for inhalation toxicity.

Mutagenicity/Carcinogenicity/Reproductive Toxicology:
Adverse effects were not found in any of the conducted studies concerning mutagenesis or carcinogenesis. In addition in a two generation study and in two teratogenicity studies only parental toxicity was found at levels well above the chronic oral NOAEL. Accordingly no DNEL- or

DMEL-values concerning mutagenesis, carcinogenicity or reproductive toxicology were derived.

DNELs for the general population

Exposure pattern	Route	Descriptors	DNEL/DMEL (appropriate unit)	Most sensitive endpoint
Acute - systemic effects	Dermal (mg/kg bw /day)	DNEL	1.54 mg/Kg	2 year repeat oral dose study
	Inhalation (mg/m^3)	DNEL	2.7 mg/m³	2 year repeat oral dose study
	Oral (mg/kg bw /day)	DNEL	1.54 mg/Kg	2 year repeat oral dose study
Acute - local effects	Dermal (mg/cm^2)	N/A		
	Inhalation (mg/m^3)	N/A		
Long-term - systemic effects	Dermal (mg/kg bw /day)	DNEL	1.54 mg/Kg	2 year repeat oral dose study
	Inhalation (mg/m^3)	DNEL	2.7 mg/m³	2 year repeat oral dose study
	Oral (mg/kg bw /day)	DNEL	1.54 mg/Kg	2 year repeat oral dose study
Long-term - local effects	Dermal (mg/cm^2)	N/A	N/A	
	Inhalation (mg/m^3)	N/A	N/A	

Discussion - Derivation of DNELs for the general population

Acute dermal local:
The acute dermal DNEL for local effects can not be determined as irritation or corrosion data showing a dose response correlation is not available.

Acute inhalative local:
The acute inhalation DNEL for local effects couldn't be derived as the irritative potential of CYA on the respiratory tract was not tested.

Acute inhalation local:
The acute inhalation DNEL for local effects couldn't be derived as the irritative potential of CYA on the respiratory tract was not tested

Acute dermal systemic:
The acute dermal DNEL for systemic effects is the same as that for long-term DNEL which is considered sufficient to ensure that these effects do not occur.

Acute inhalation systemic:
The acute dermal DNEL for systemic effects is the same as that for long-term DNEL which is considered sufficient to ensure that these effects do not occur.

Acute oral systemic:
The acute dermal DNEL for systemic effects is the same as that for long-term DNEL which is considered sufficient to ensure that these effects do not occur

Long-term dermal systemic:
The long-term dermal DNEL for systemic effects is calculated based on a route to route extrapolation from a chronic oral drinking water study assuming complete absorption via the dermal route which is a very conservative assumption given the low dermal permeability.
The starting value is the NOAEL (oral, rat chronic) of 154 mg/Kg.
The assessment factor is the product of:
- factor for route-to-route extrapolation: 1.0
- interspecies factor: 2.5
- allometric scaling: 4.0
- intra species factor for general public: 10
- total assessment factor (product of assessment factors): 100
- total factor (product of assessment factors x route-to-route factor): 100
- derived long-term dermal DNEL for systemic effects: 1.54 mg/Kg bw

Long-term inhalative systemic:

The long-term inhalation DNEL for systemic effects is calculated based on a route to route extrapolation from a chronic oral drinking water study.
The starting value is the NOAEL (oral, rat chronic) of 154 mg/Kg.
To convert this into a NAEC for the general population the following calculation is applied:
154 mg/Kg /4 x 70 kg bw /20 m^3 = 134.75 mg/m^3 (NAEC general public 24 h)
An assessment factor of 4 is applied to correct for differences in metabolic rate per body weight.
The following assessment factors are then applied.
AF of 2.5 (default) is applied for remaining interspecies differences.
AF of 10 is applied for intraspecies differences for the general public.
AF of 2 is applied for route to route extrapolation of oral to inhalation exposure.
The total AF applied is obtained by multiplication of all the assessment factors (2.5 * 10 * 2) giving an overall assessment factor of 50.
The inhalation general public DNEL for systemic effects is 134.75 mg/m^3 /50 = 2.7 mg/m^3.

Long-term oral systemic:
The long-term oral DNEL for systemic effects is calculated based a chronic oral drinking water study in rats.
The starting value is the NOAEL (oral, rat, chronic) of 154 mg/Kg.
The assessment factor is the product of:
- interspecies factor: 2.5
- allometric scaling: 4.0
- intra species factor for general public: 10
- total assessment factor (product of assessment factors): 100
- derived long-term oral DNEL for systemic effects: 1.54 mg/Kg bw

Long-term dermal local:
The long-term dermal DNEL for local effects couldn't be derived as results from repeated dose experiments are not available for dermal toxicity.

Long-term inhalative local:
The long-term inhalation DNEL for local effects couldn't be derived as results from repeated dose experiments are not available for inhalation toxicity.

Mutagenicity/Carcinogenicity/Reproductive Toxicology:
Adverse effects were not found in any of the conducted studies concerning mutagenesis or carcinogenesis. In addition in a two generation study and in two teratogenicity studies only parental toxicity was found at levels well above the chronic oral NOAEL. Accordingly no DNEL- or DMEL-values concerning mutagenesis, carcinogenicity or reproductive toxicology were derived.

3 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

3.1 Explosivity

CYA does not contain any chemical groups identified as potentially explosive within the molecule and therefore is not expected to be explosive.

3.2 Flammability

CYA is not flammable as demonstrated in EU Method A.10. (Atwal SS & Tremain SP 2009)

3.3 Oxidising potential

The chemical structure of CYA establishes that it is incapable of reacting exothermically with a combustible material and therefore has no oxidizing potential.

4 ENVIRONMENTAL HAZARD ASSESSMENT

4.1 Aquatic compartment (including sediment)

4.1.1 Toxicity data

4.1.1.1 Fish

4.1.1.1.1 Short-term toxicity to fish

Table 20. Marine and freshwater fish acute studies

Guideline/ Test method	Test substance	Species	Exposure		Results (mg/l) measured			Ref.
			design	duration	LC_0	LC_{50}	LC_{100}	
Comparable to OECD 203	CYA	*Lepomis macrochirus*	static	96 h		>1000		Thompson CM, Forbis AD (1978a)
Comparable to OECD 203	CYA	*Salmo gairdneri*	static	96 h		>2100		Thompson CM, Forbis AD (1978b)
Comparable to OECD 203	CYA	*Pimephales promelas*	static	96 h		>2100		Thompson CM, Forbis AD (1978c)
EPA/600/4-90/027	CYA	Inland silversides	static	96 h		8000		Anderson K (2002)

4.1.1.1.2 Long-term toxicity to fish

Table 21. Fish juvenile growth test

Guideline/ Test method	Test substance	Species	Endpoint	Exposure duration	Results (mg/l) measured			Remarks	Ref.
					Effect	NOEC	LOEC		
OECD 215 Fish juvenile growth test	Monosodium salt of CYA (75.6% CYA)	Rainbow Trout	growth	21 days	No effects noted at limit dose	756 as CYA	> 756 as CYA	Zero mortalities, no inhibition of tank average specific growth rate, no sublethal effects of exposure and no significant reduction in terms of the "pseudo" specific growth rate when compared to the control group. Results corrected for cyanuric acid content. Test material equivalent to 75.6 % by weight of	Sewell IG, Mullee DM (2007)

								cyanuric acid. Fish exposed to dissolved and dispersed test material.	

4.1.1.2 Aquatic invertebrates

4.1.1.2.1 Short-term toxicity to aquatic invertebrates

Table 22. Toxicity to *Daphnia magna*

Guideline/ Test method	Test substance	Species	Exposure		Results (mg/l) measured			Ref.
			design	duration	EC_0	EC_{50}	EC_{100}	
Comparable to OECD 202	CYA	*Daphnia magna*	static	48 h		>1000		McAllister WA, Thompson CM (1978)

4.1.1.2.2 Long-term toxicity to aquatic invertebrates

Table 23. Reproduction test in *Daphnia magna*

Guideline / Test method	Test substance	Species	Endpoint	Exposure duration	Results (mg/l) measured		Remarks	Ref.
					NOEC	LC_{50}		
OECD 211	Monosodium salt of CYA (75.6% CYA)	*Daphnia magna*	Reproduction	21-days	121 as CYA	2117 as CYA (reproduction)	NOEC based on significant mortalities in the adult (F_1) generation and fewer live young per adult. Results corrected for cyanuric acid content. Test material equivalent to 75.6% by weight of cyanuric acid.	Sewell IG, Hill JWF (2007)

4.1.1.3 Algae and aquatic plants

Table 24. Algal toxicity

Guideline/ Test method	Test substance	Species	Endpoint	Exposure duration	Results (mg/l) measured		Remarks	Ref.
					NOEC	EC_{50}		
OECD 201	Monosodium salt of CYA (75.6% CYA)	*Navicula pelliculosa*	Growth	96 h	945 as CYA	3780 as CYA	The test material has a growth delaying effect on algal cells over the first 72 hours of the study. The cells recover after 96 hours to match control values. Results corrected for cyanuric acid content. Test material equivalent to 75.6% by weight of cyanuric acid.	Vryenhoef H, Hill JWF (2007)
ISO Guideline No. 10253 'Water Quality Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum'*	Monosodium salt of CYA (75.6% CYA)	*Skeletonema costatum*	Growth	96 h	>76 as CYA	76 as CYA	Based on nominal concentrations.	Vryenhoef H, Mullee D (2008)
Similar to US EPA (1971) Algal Assay Procedure: Bottle test	CYA	*Selenastrum capricornutum*	Phytotoxicity: Chlorophyll conc. Cell No.	96 h		 712 655	Nominal concentrations only. No NOEC concentration reported.	Hollister TA (1978)

4.1.1.4 Sediment organisms

Table 25. Toxicity to chironomid

Guideline/ Test method	Test material	Spp.	End point	Exposure duration		Results (mg/kg dwt) measured		Remarks	Ref.
				design	duration	NOEC	EC_{50}		
OECD 218	Monosodium salt of CYA (75.6% CYA)	Chironomid	emergence	static	28 days	756 as CYA	> 756 as CYA	Results corrected for cyanuric acid content. Test material equivalent to 75.6% by weight of cyanuric acid.	Goodband TJ, Mullee DM (2007)

4.1.1.5 Other aquatic organisms

Table 26. Toxicity to mysid shrimp

Guideline/ Test method	Test substance	Species	Exposure		Results (mg/l) measured			Remarks	Ref.
			design	duration	EC_0	EC_{50}	EC_{100}		
EPA/600/4-90/027	CYA	*Mysid shrimp*	static	48 h		4438		Nominal concentrations only.	Anderson K (2002)

4.1.2 Calculation of Predicted No Effect Concentration (PNEC)

4.1.2.1 PNEC water

Table 27. PNEC aquatic

	Value	Assessment factor	Remarks/Justification
PNEC aqua – freshwater (mg/l)	12.1	10	On the basis of acute and chronic toxicity data against fish, invertebrates and algae, it is possible to derive a PNEC for aquatic organisms from the lowest NOEC from chronic studies and applying a safety factor of 10. Based upon the available data the lowest NOEC for CYA is from the Daphnia reproduction study (121 mg/l).
PNEC aqua - marine water (mg/l)	1.52	50	Three long term NOECS are available for freshwater species plus one long term NOEC from the marine algal test. The lowest NOEC is from the marine algal test which gives a NOEC of 76 mg/L. An assessment factor of 50 is applied.

4.1.2.2 PNEC sediment

Table 28. PNEC sediment

	Value	Assessment factor	Remarks/Justification
PNEC sediment (mg/kg d.w.)	7.56	100	There were no effects at the limit dose level on Chironomid. The PNEC for sediment is derived by applying an assessment factor of 100 to lowest value, the NOEC or EC_{10}, from a long-term sediment study. In this case the NOEC and EC_{10} are both >= 756 mg/kg dwt.

4.2 Terrestrial compartment

4.2.1 Toxicity data

4.2.1.1 Toxicity to soil macro organisms

Table 29. Earthworm toxicity

Guideline/ Test method	Test substance	Spp.	Endpoint	Exposure duration	Results (mg/kg dwt) measured		Remarks	Ref.
					NOEC	LC_{50}		
OECD 207	Monosodium salt of CYA	Earth-worm	Acute toxicity	14-days	756 as CYA	>756 as CYA	Results corrected for cyanuric acid content. Test material equivalent to 75.6 % by weight of cyanuric acid.	Goodband TJ (2007)

CYA is not toxic to earthworms.

4.2.2 Calculation of Predicted No Effect Concentration (PNEC_soil)

Table 30. PNEC soil

	Value	**Assessment factor**	**Remarks/Justification**
PNEC soil (mg/kg.dwt.)	0.756	1000	The PNEC is derived from the LC50 earthworm acute toxicity as this is the only available terrestrial test.

4.3 Atmospheric compartment

The vapour pressure of CYA is 0.000001 Pa at 25°C. The calculated (see 4.1.5) Henry's Law Constant (at 25°C) is 0.000000086 $Pa \cdot m^3 \cdot mol^{-1}$. Atmospheric exposure is not anticipated.

4.4 Microbiological activity in sewage treatment systems

4.4.1 Toxicity to aquatic micro-organisms

Table 31. Activated sludge respiration inhibition

Guideline/ Test method	Test substance	Spp.	Exposure duration	Results (mg/l) measured		Remarks	Ref.
				NOEC	EC_{50}		

OECD Guideline 209, "Activated Sludge, Respiration inhibition Test"	Monosodium salt of CYA (75.6% CYA)	Activated sludge, predominantly domestic sewage	3h	2041 as CYA	3402 as CYA	Results corrected for cyanuric acid content. Test material equivalent to 75.6% by weight of cyanuric acid. Highest test concentration based on maximum limit of solubility of the test material.	Clarke N (2007)

4.4.2 PNEC for sewage treatment plant

Table 32. PNEC sewage treatment plant

	Value	**Assessment factor**	**Remarks/Justification**
PNEC stp (mg/l)	204.1	10	PNEC based on the NOEC of 2041 mg/l from the ASRI study.

4.5 Non compartment specific effects relevant for the food chain (secondary poisoning)

4.5.1 Toxicity to birds

Table 33. Toxicity to birds

Guideline/ Test method	Test substance	Species	Endpoint	Exposure duration	Results (mg/kg) measured	Ref.
					LD50	
Not stated	Monosodium cyanurate	Bobwhite quail	Mortality	8 days	>10000	Fink R (1975)
Not stated	Monosodium cyanurate	Mallard duck	Mortality	8 days	> 10000	Fink R (1975)

4.5.2 Toxicity to mammals

A study in cats was performed to characterize the toxicity potential of melamine, cyanuric acid and a combination of melamine and cyanuric acid (Puschner B et al 2007). Cyanuric acid was added to the diet of 1 cat at increasing doses of 0.2%, 0.5%, and 1% over the course of 10 days. CYA administered alone even at a high dose of 234 mg/kg did not have any effect on renal function of cats based upon normal serum creatinine and urea nitrogen concentrations. No gross or histologic abnormalities were present. There was no observed effect on renal function in one cat fed 49 - 234 mg/kg/day of CYA for a total of 10 days.

4.6 Conclusion on the environmental classification and labelling

CYA is not classified for the environment.

5 PBT AND VPVB ASSESSMENT

5.1 Assessment of PBT/vPvB properties – Comparison with the criteria of Annex XIII

5.1.1 Persistence assessment

According to Annex XIII of the REACH regulations the criteria for persistence is $T_{½}$ in fresh water sediment or $T_{½}$ in soil >120 days. In biodegradation studies with soil and sediments CYA degrades rapidly in a variety of soils attaining 52%-100% degradation in 23 days.

5.1.2 Bioaccumulation assessment

According to Annex XIII of the REACH regulations the criteria for bioaccumulation is BCF>2000. CYA has a BCF value of 6.36 and therefore there is no potential for bioaccumulation to occur.

5.1.3 Toxicity assessment

According to Annex XIII of the REACH regulations the criteria for toxicity is a NOEC<0.01 mg/l for marine or freshwater organisms or classification as carcinogenic, mutagenic or toxic for reproduction (CMR) or classification for chronic toxicity according to directive 67/548/EEC. The lowest aquatic toxicity endpoint for CYA is a NOEC of 121 mg/l in a chronic toxicity study with *Daphnia magna* (Sewell IG,Hill JWF 2007) and CYA is not classified as a CMR or for chronic toxicity.

5.1.4 Summary and overall conclusions on PBT or vPvB properties

The exposure assessment and risk characterisation only needs to be performed if the substance is identified as a PBT, vPvB or meets the criteria for classification as dangerous according to Directive 67/548/EEC or directive 1999/45/EEC.

Cyanuric acid is not PBT or vPvB and does not meet the criteria for classification as dangerous and therefore the exposure assessment and risk characterisation sections of the chemical safety report are not required.