Ficha de datos de seguridad

11/2/2014, Revisión 8 (453/2010)

SECCIÓN 1: Identificación de la sustancia o la mezcla y de la sociedad o la empresa

1.1. Identificador del producto

Identificación de la sustancia

Nombre comercial: CTX-400 Estabilizante de Cloro
Número CAS: 108-80-5
Número EC: 203-618-0
Producto homologado por la D.G.S.P.
Número REACH: 01-2119480421-45-XXXX

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

Uso recomendado:
Estabilizante de cloro
Usos no recomendados:
No se ha identificado ninguno.

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

Proveedor:
CERTIKIN POOL IBERICA, S.L.U
Passeig Sanllehy, 23
08213 POLINYA (Barcelona) - Spain
Tel.: 34 93 714 96 32
Fax: 34 93 713 12 91
www.certikiniberica.com

Persona competente responsable de la ficha de datos de seguridad:
fds@certikiniberica.com

1.4. Teléfono de emergencia

Centros de Información Toxicológica:

ESPAÑA: +34 91 562 04 20

FRANCIA (Paris): 01 40 05 48 48
FRANCIA (Tolousse): 05 61 77 74 47
FRANCIA (Marseille): 04 91 75 25 25

ITALIA (Roma): 06/305 43 43
ITALIA (Milan): 02/66 10 10 29

PORTUGAL: 808 250 143

SECCIÓN 2: Identificación de los peligros

2.1. Clasificación de la sustancia o de la mezcla

Criterios de las Directivas 67/548/CE, 99/45/CE siguientes actualizaciones:
Propiedades / Símbolos:

 Xi Irritante

Frases R:

R36 Irrita los ojos.

Criterios Reglamentación CE 1272/2008 (Clasificación, Etiquetado y Empacado):

 Atención, Eye Irrit. 2, Provoca irritación ocular grave.

Efectos físico-químicos nocivos para la salud humana y para el medio ambiente:

Ningún otro riesgo

2.2. Elementos de la etiqueta
Símbolos:

Atención
Indicaciones de Peligro:
H319 Provoca irritación ocular grave.
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.
P261 Evitar respirar el polvo.
P262 Evitar el contacto con los ojos, la piel o la ropa.
P270 No comer, beber ni fumar durante su utilización.
P280 Llevar guantes/prendas/gafas/máscara de protección.
P309+P311 EN CASO DE exposición o si se encuentra mal: Llamar inmediatamente a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico.
Disposiciones especiales:
Ninguna.
Ninguna.
2.3. Otros peligros
Sustancias vPvB: Ninguna. - Sustancias PBT: Ninguna.
Otros riesgos:
Ningún otro riesgo
En contacto con los ojos el producto provoca irritaciones importantes que pueden durar más de 24 horas.

SECCIÓN 3: Composición/información sobre los componentes

3.1. Sustancias
Identificación de la sustancia
Sustancias peligrosas:
Número CAS: 108-80-5
Número EC: 203-618-0
Número REACH: 01-2119480421-45-XXXX

Componentes peligrosos según la Directiva CEE 67/548 y el Reglamento CLP y su correspondiente clasificación:
>= 90% acido isocianurico
REACH No.: 01-2119480421-45-XXXX, CAS: 108-80-5, EC: 203-618-0
Xi; R36
3.3/2 Eye Irrit. 2 H319

3.2. Mezclas
N.D.

SECCIÓN 4: Primeros auxilios

4.1. Descripción de los primeros auxilios
Retire a la persona de la zona contaminada.
Si la persona está inconsciente, acuéstela de lado con la cabeza más baja y las rodillas

semiflexionadas.
Conserve la temperatura corporal
Traslade al intoxicado a un centro hospitalario y, siempre que sea posible, lleve la etiqueta o el envase.

En caso de contacto con la piel:
Quítese inmediatamente la ropa contaminada.
Lavar inmediatamente con abundante agua corriente y eventualmente jabón las zonas del cuerpo que han entrado en contacto con el producto, incluso si fuera sólo una sospecha.
Lavar completamente el cuerpo (ducha o baño).
Quitarse de inmediato la indumentaria contaminada y eliminarla de manera segura.
En caso de contacto con la piel, lavar de inmediato con abundante agua y jabón.

En caso de contacto con los ojos:
En caso de contacto con los ojos, enjugarlos con agua durante un tiempo adecuado y manteniendo los párpados abiertos, luego consultar de inmediato con un oftalmólogo.
Proteger el ojo ileso.

En caso de ingestión:
No administrar nada por vía oral.
No provocar el vómito en ningún caso. CONSULTAR INMEDIATAMENTE AL MÉDICO.

En caso de inhalación:
Llevar al accidentado al aire libre y mantenerlo en reposo y abrigado.
Airee el lugar. Haga salir inmediatamente al paciente del lugar contaminado y manténgalo en reposo en un lugar bien aireado. LLAME AL MÉDICO.

4.2. Principales síntomas y efectos, agudos y retardados
Contacto con los ojos: Irritación.
Contacto con la piel: Irritación.
Ingestión: irritación de mucosas y tracto gastrointestinal.
Inhalación: irritación de mucosas y tracto respiratorio.

4.3. Indicación de toda atención médica y de los tratamientos especiales que deban dispensarse inmediatamente
En caso de accidente o malestar, consultar de inmediato con un médico (si es posible mostrarle las instrucciones de uso o la ficha de seguridad)
Tratamiento:
Tratamiento sintomático.

SECCIÓN 5: Medidas de lucha contra incendios

5.1. Medios de extinción
Medios de extinción apropiados:
Agua, CO2, espuma, polvo químico según los materiales implicados en el incendio.
Medios de extinción que no se deben utilizar por motivos de seguridad:
Ninguno en particular.

5.2. Peligros específicos derivados de la sustancia o la mezcla
Evite respirar los humos.
No inhalar los gases producidos por la explosión y por la combustión.
La combustión produce humo pesado.

5.3. Recomendaciones para el personal de lucha contra incendios
Utilizar equipos respiratorios apropiados.
Recoger por separado el agua contaminada utilizada para extinguir el incendio. No descargarla en la red de alcantarillado.
Si es posible, desde el punto de vista de la seguridad, retirar de inmediato del área los contenedores no dañados.

SECCIÓN 6: Medidas en caso de vertido accidental

6.1. Precauciones personales, equipo de protección y procedimientos de emergencia
Usar los dispositivos de protección individual.
Llevar las personas a un lugar seguro.
Consultar las medidas de protección expuestas en los puntos 7 y 8.

6.2. Precauciones relativas al medio ambiente

Evitar que el producto penetre en el suelo/subsuelo. Evitar que penetre en aguas superficiales o en el alcantarillado.
Conservar el agua de lavado contaminada y eliminarla.
En caso de fuga de gas o penetración en cursos de agua, suelo o sistema de alcantarillado, informar a las autoridades responsables.
Material apropiado para la recogida: material absorbente, orgánico, arena

6.3. Métodos y material de contención y de limpieza

Lavar con abundante agua.

6.4. Referencia a otras secciones

Véanse también los apartados 8 y 13.

SECCIÓN 7: Manipulación y almacenamiento

7.1. Precauciones para una manipulación segura

Evitar el contacto con la piel y los ojos, la inhalación de vapores y vahos.
No utilizar contenedores vacíos que no hayan sido previamente limpiados.
Antes de realizar las operaciones de transferencia, asegurarse de que en los contenedores no haya materiales residuos incompatibles.
La indumentaria contaminada debe ser sustituida antes de acceder a las áreas de almuerzo.
No comer ni beber durante el trabajo.
Remitirse también al apartado 8 para los dispositivos de protección recomendados.

7.2. Condiciones de almacenamiento seguro, incluidas posibles incompatibilidades

Almacenar en el recipiente original.
Guardar en lugar seco.
Manténgase el recipiente cerrado.
Mantener alejado de comidas, bebidas y piensos.
Materias incompatibles:
Ninguna en particular.
Indicaciones para los locales:
Locales adecuadamente aireados.

7.3. Usos específicos finales

Ningún uso particular

SECCIÓN 8: Controles de exposición/protección individual

8.1. Parámetros de control

No se dispone de ningún límite de exposición profesional

Valores límites de exposición DNEL

N.D.

Valores límites de exposición PNEC

N.D.

8.2. Controles de la exposición

Protección de los ojos:

Gafas.

Protección de la piel:

No se requiere ninguna precaución especial para el uso normal.

Protección de las manos:

Utilizar guantes de protección que garanticen una protección total, por ejemplo de PVC, neopreno o caucho.

Protección respiratoria:

Utilizar una protección respiratoria adecuada.

Riesgos térmicos:

Ninguno

Controles de la exposición ambiental:

Ninguno

SECCIÓN 9: Propiedades físicas y químicas

9.1. Información sobre propiedades físicas y químicas básicas

Estado físico:	Sólido
Aspecto y color:	Blanco
Olor:	Inodoro
Umbral de olor:	N.D.
pH:	2 - 3 (20 ºC)
Punto de fusión/congelamiento:	> 360 ºC
Punto de ebullición inicial e intervalo de ebullición:	> 300 ºC
Inflamabilidad sólidos/gases:	N.D.
Límite superior/inferior de inflamabilidad o explosión:	N.D.
Densidad de los vapores:	N.D.
Punto de ignición (flash point, fp):	N.D.
Velocidad de evaporación:	N.D.
Presión de vapor:	N.D.
Densidad relativa:	1.75 g/ml (ºC)
Hidrosolubilidad:	2000 mg/l (25ºC)
Coeficiente de reparto (n-octanol/agua):	- 1.31 (25ºC)
Temperatura de autoencendido:	N.D.
Temperatura de descomposición:	375ºC
Viscosidad:	N.D.
Propiedades explosivas:	Si entra en contacto con: (ver punto 10)
Propiedades comburentes:	No

9.2. Información adicional

Miscibilidad:	N.D.
Liposolubilidad:	N.D.
Conductibilidad:	N.D.
Propiedades características de los grupos de sustancias	N.D.

SECCIÓN 10: Estabilidad y reactividad

10.1. Reactividad

Estable en condiciones normales

10.2. Estabilidad química

Estable en condiciones normales

10.3. Posibilidad de reacciones peligrosas

La descomposición térmica da lugar a la formación de ACIDO CIANICO en presencia de dióxido de carbono (residuo de la combustión de otras materias). El ácido ciánico es ALTAMENTE TOXICO y puede ser causa de explosiones.

10.4. Condiciones que deben evitarse

Estable en condiciones normales.

10.5. Materiales incompatibles

Ácidos, bases y materias reactivas en general.

10.6. Productos de descomposición peligrosos

Ninguno.

SECCIÓN 11: Información toxicológica

11.1. Información sobre los efectos toxicológicos

Informaciones toxicológicas relativas a la mezcla:

N.D.

Informaciones toxicológicas relativas a la sustancia:

acido isocianurico - CAS: 108-80-5

a) toxicidad aguda:

Test: LD50 - Vía: Oral - Especies: Rata > 5000 mg/kg

Test: LD50 - Vía: Piel - Especies: Rata > 5000 mg/kg

Test: LC50 - Vía: Inhalación - Especies: Rata > 5.25 mg/l

b) corrosión o irritación cutáneas:

Test: Irritante para la piel - Vía: Piel Negativo

c) lesiones o irritación ocular graves:

Test: Irritante para los ojos Negativo

d) sensibilización respiratoria o cutánea:
Test: Sensibilización de la piel Negativo
e) mutagenicidad en células germinales:
Test: Mutagénesis Negativo
g) toxicidad para la reproducción:
Test: Toxicidad para la reproducción Negativo

Si no se especifica de otra forma, los datos requeridos por el Reglamento 453/2010/CE que se indican abajo deben considerarse N.A.:
a) toxicidad aguda;
b) corrosión o irritación cutáneas;
c) lesiones o irritación ocular graves;
d) sensibilización respiratoria o cutánea;
e) mutagenicidad en células germinales;
f) carcinogenicidad;
g) toxicidad para la reproducción;
h) toxicidad específica en determinados órganos (STOT) – exposición única;
i) toxicidad específica en determinados órganos (STOT) – exposición repetida;
j) peligro de aspiración.

SECCIÓN 12: Información ecológica

12.1. Toxicidad
Utilícese con técnicas de trabajo adecuadas, evitando la dispersión del producto en el medio ambiente.
acido isocianurico - CAS: 108-80-5
a) Toxicidad acuática aguda:
Parámetro: LC50 - Especies: Peces = 2100 mg/l - Duración h.: 96
Parámetro: EC50 - Especies: Algas = 3780 mg/l - Duración h.: 96
12.2. Persistencia y degradabilidad
Ninguno
N.D.
12.3. Potencial de bioacumulación
N.D.
12.4. Movilidad en el suelo
N.D.
12.5. Resultados de la valoración PBT y mPmB
Sustancias vPvB: Ninguna. - Sustancias PBT: Ninguna.
12.6. Otros efectos adversos
Ninguno

SECCIÓN 13: Consideraciones relativas a la eliminación

13.1. Métodos para el tratamiento de residuos
Recuperar si es posible. Enviar a centros de eliminación autorizados o a incineración en condiciones controladas. Operar conforme con las disposiciones locales y nacionales vigentes.

SECCIÓN 14: Información relativa al transporte

14.1. Número ONU
Producto no peligroso según los criterios de la reglamentación del transporte.
14.2. Designación oficial de transporte de las Naciones Unidas
N.D.
14.3. Clase(s) de peligro para el transporte
N.D.
14.4. Grupo de embalaje
N.D.
14.5. Peligros para el medio ambiente
N.D.

14.6. Precauciones particulares para los usuarios
N.D.
14.7. Transporte a granel con arreglo al anexo II del Convenio Marpol 73/78 y del Código IBC
N.D.

SECCIÓN 15: Información reglamentaria

15.1. Reglamentación y legislación en materia de seguridad, salud y medio ambiente específicas para la sustancia o la mezcla
Dir. 67/548/CEE (Clasificación, embalaje y etiquetado de sustancias peligrosas)
Dir. 99/45/CE (Clasificación, envasado y etiquetado de preparados peligrosos)
Dir. 98/24/CE (Riesgos relacionados con los agentes quí?micos durante el trabajo)
Dir. 2000/39/CE (Valores límite de exposición profesional)
Dir. 2006/8/CE
Reglamento (CE) n. 1907/2006 (REACH)
Reglamento (CE) n. 1272/2008 (CLP)
Reglamento (CE) n. 790/2009 (ATP 1 CLP) y (UE) n. 758/2013
Reglamento (UE) n. 453/2010 (Anexo I)
Reglamento (UE) n. 286/2011 (ATP 2 CLP)
Cuando sean aplicables, hágase referencia a las siguientes normativas:
Directiva 82/501/CEE ('Actividades ligadas al riesgo de accidentes graves') y subsiguientes enmiendas.
Reglamento (CE) no 648/2004 (detergentes).
1999/13/CE (directiva COV)

15.2. Evaluación de la seguridad química
No

SECCIÓN 16: Otra información

Texto de las frases utilizadas en el parágrafo 3:
R36 Irrita los ojos.

H319 Provoca irritación ocular grave.
Parágrafos modificados respecto la revisión anterior:

SECCIÓN 1: Identificación de la sustancia o la mezcla y de la sociedad o la empresa
SECCIÓN 2: Identificación de los peligros
SECCIÓN 3: Composición/información sobre los componentes
SECCIÓN 14: Información relativa al transporte
SECCIÓN 15: Información reglamentaria

Este documento ha sido preparado por una persona competente que ha recibido un entrenamiento adecuado
Principales fuentes bibliográficas:
ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities
SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold
CCNL - Allegato 1 "TLV de 1989-90"
Indicar bibliografía adicional consultada
La información aquí detallada se basa en nuestros conocimientos hasta la fecha señalada arriba. Se refiere exclusivamente al producto indicado y no constituye garantía de cualidades particulares.
El usuario debe asegurarse de la idoneidad y exactitud de dicha información en relación al uso específico que debe hacer del producto.
Esta ficha anula y sustituye toda edición precedente.

ADR: Acuerdo europeo relativo al transporte internacional de mercancías peligrosas por carretera.

CAS:	Chemical Abstracts Service (de la American Chemical Society).
CLP:	Clasificación, etiquetado, embalaje.
DNEL:	Nivel sin efecto derivado.
EINECS:	Catálogo Europeo de Sustancias Químicas Comercializadas.
GefStoffVO:	Ordenanza sobre sustancias peligrosas, Alemania.
GHS:	Sistema Globalmente Armonizado de clasificación y etiquetado de productos químicos.
IATA:	Asociación de Transporte Aéreo Internacional.
IATA-DGR:	Normas aplicadas a las mercancías peligrosas por la "Asociación de Transporte Aéreo Internacional" (IATA).
ICAO:	Organización de la Aviación Civil Internacional.
ICAO-TI:	Instrucciones Técnicas de la "Organización de la Aviación Civil Internacional" (OACI).
IMDG:	Código marítimo internacional de mercancías peligrosas.
INCI:	Nomenclatura internacional de ingredientes cosméticos.
KSt:	Coeficiente de explosión.
LC50:	Concentración letal para el 50% de la población expuesta.
LD50:	Dosis letal para el 50% de la población expuesta.
LTE:	Exposición a largo plazo.
PNEC:	Concentración prevista sin efecto.
RID:	Normas relativas al transporte internacional de mercancías peligrosas por ferrocarril.
STE:	Exposición a corto plazo.
STEL:	Nivel de exposición de corta duración.
STOT:	Toxicidad específica en determinados órganos.
TLV:	Valor límite del umbral.
TWATLV:	Valor límite del umbral para el tiempo medio ponderado de 8 horas por día (Estándar ACGIH).
WGK:	Clase de peligro para las aguas (Alemania).
N.A.:	N.D.
N.D.:	No disponible

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 Total	Urine	Blood	Skin	Washings	Reference
^{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 (%) Total	Urine	Reference
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.