Toelatingsnummer 7321 N

Suma Tab D4

7321 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

Dit besluit is een rectificatie van het besluit van 29 oktober 2010. Het besluit van 29 oktober 2010 komt te vervallen. Het volgende is gerectificeerd: Het gevaarsymbool "O" (oxiderend) en de waarschuwingszin R8 (Bevordert de ontbranding van brandbare stoffen) komen te vervallen.

1 VERLENGING TOELATING

Gelet op de aanvraag d.d. 21 september 2007 (20070990 TVB) van

Diversey B.V.
Maarssenbroeksedijk 2
3542 DN UTRECHT

tot verlenging van de toelating voor de biocide, op basis van de werkzame stof natriumdichloorisocyanuraat

Suma Tab D4

gelet op artikel 122, Wet gewasbeschermingsmiddelen en biociden,

BESLUIT HET COLLEGE als volgt:

1.1 Verlenging toelating

1. De toelating van het middel Suma Tab D4, welke expireert op 1 november 2010 wordt voor de in bijlage I genoemde toepassingen verlengd onder nummer 7321. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.
2. De toelating geldt tot het tijdstip waarop de lidstaten maatregelen genomen hebben om de nationale toelating in overeenstemming te brengen met het besluit over de werkzame stof van de Europese Commissie.

1.2 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.3 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage I onder A bij dit besluit is voorgeschreven.

1.4 Classificatie en etikettering

Gelet op artikel 50, eerste lid, sub d, Wet gewasbeschermingsmiddelen en biociden,

1. De aanduidingen, welke ingevolge artikelen 9.2.3.1 en 9.2.3.2 van de Wet milieubeheer en artikelen 14, 15a, 15b, 15c en 15d van de Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten op de verpakking moeten worden vermeld, worden hierbij vastgesteld als volgt:

   aard van het preparaat: Tablet

werkzame stof:	*gehalte:*
natriumdichloorisocyanuraat	85 %

<u>letterlijk en zonder enige aanvulling:</u>

andere zeer giftige, giftige, bijtende of schadelijke stof(fen):
-

gevaarsymbool:	*aanduiding:*
Xn	Schadelijk
N	Milieugevaarlijk

Waarschuwingszinnen:

R22	-Schadelijk bij opname door de mond.
R31	-Vormt vergiftige gassen in contact met zuren.
R36/37	-Irriterend voor de ogen en de ademhalingswegen.
R50/53	-Zeer vergiftig voor in het water levende organismen; kan in het aquatisch milieu op lange termijn schadelijke effecten veroorzaken.

Veiligheidsaanbevelingen:

S08	-Verpakking droog houden.
S21	-Niet roken tijdens gebruik.
S22/23-NL	-Stof en spuitnevel niet inademen.
S36/37/39b	-Draag geschikte beschermende kleding, handschoenen en een beschermingsmiddel voor het gezicht.
S60	-Deze stof en de verpakking als gevaarlijk afval afvoeren. (Deze zin hoeft niet te worden vermeld op het etiket indien u deelneemt aan het verpakkingenconvenant, en op het etiket het STORL-vignet voert, en ingevolge dit convenant de toepasselijke zin uit de volgende verwijderingszinnen op het etiket vermeldt: Deze verpakking is bedrijfsafval, mits deze is schoongespoeld, zoals wettelijk is voorgeschreven. Deze verpakking is bedrijfsafval, nadat deze volledig is geleegd. Deze verpakking dient nadat deze volledig is geleegd te worden ingeleverd bij een KCA-depot. Informeer bij uw gemeente.)
S61	-Voorkom lozing in het milieu. Vraag om speciale instructies / veiligheidsgegevenskaart.

Specifieke vermeldingen:

-

1) Behalve de onder 1. bedoelde en de overige bij de Wet Milieugevaarlijke Stoffen en Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten voorgeschreven

aanduidingen en vermeldingen moeten op de verpakking voorkomen:

- letterlijk en zonder enige aanvulling:
  het wettelijk gebruiksvoorschrift
  De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I, onder A.

- hetzij letterlijk, hetzij naar zakelijke inhoud:
  de gebruiksaanwijzing
  De tekst van de gebruiksaanwijzing is opgenomen in Bijlage I, onder B.
  De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.

2 DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraag

De toelating van het middel Suma Tab D4 is laatstelijk bij besluit d.d. 8 december 2000 verlengd tot 1 november 2010. Het betreft een aanvraag tot verlenging van de toelating van het middel Suma Tab D4 (7321 N), een middel op basis van de werkzame stof natriumdichloorisocyanuraat. De verlenging wordt aangevraagd voor de toelating als middel ter bestrijding van:

1. bacteriën incl. mycobacteriën excl. bacteriesporen en gisten op oppervlakken, welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor.
2. bacteriën incl. mycobacteriën excl. bacteriesporen en gisten op oppervlakken in ruimten bestemd voor het verblijf van mensen.
3. bacteriën excl. Mycobacteriën excl. bacteriesporen en gisten in dierverblijfplaatsen en bijbehorende ruimten.
4. bacteriën excl. Mycobacteriën excl. bacteriesporen, gisten en virussen in transportmiddelen voor dieren.

2.2 Informatie met betrekking tot de stof

-

2.3 Karakterisering van het middel

-

2.4 Voorgeschiedenis

De aanvraag is op 21 september 2007 ontvangen; op 19 september 2007 en 22 juli 2010 zijn de verschuldigde aanvraag- en beoordelingskosten ontvangen.

2.5 Eindconclusie

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel Suma Tab D4 op basis van de werkzame stof natriumdichloorisocyanuraat voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu (artikel 28, Wet gewasbeschermingsmiddelen en biociden).

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 119, eerste lid, Wet gewasbeschermingsmiddelen en biociden en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 17 december 2010

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

dr. D. K. J. Tommel
voorzitter

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I bij het besluit d.d. 17 december 2010 tot verlenging van de toelating van het middel Suma Tab D4, toelatingnummer 7321 N

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van:
1. bacteriën incl. mycobacteriën excl. bacteriesporen en gisten op oppervlakken, welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor.
2. bacteriën incl. mycobacteriën excl. bacteriesporen en gisten op oppervlakken in ruimten bestemd voor het verblijf van mensen.
3. bacteriën excl. Mycobacteriën excl. bacteriesporen en gisten in dierverblijfplaatsen en bijbehorende ruimten.
4. bacteriën excl. Mycobacteriën excl. bacteriesporen, gisten en virussen in transportmiddelen voor dieren.

In combinatie met het reinigingsmiddel Suma Total D2.4 en Suma Total D2.4 conc. is het gebruik uitsluitend toegestaan als middel ter bestrijding van bacteriën incl. mycobacteriën excl. bacteriesporen en gisten op oppervlakken, welke in contact kunnen komen met eet- en drinkwaren en de grondstoffen hiervoor echter met uitzondering van melkwinningsapparatuur op de boerderij, alsmede in ruimten bestemd voor het verblijf van mensen, volgens de in de gebruiksaanwijzing gegeven dosering en werkwijze.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Het middel is bestemd voor de desinfectie van oppervlakken, apparatuur en gebruiksvoorwerpen.

De te desinfecteren oppervlakken en materialen eerst grondig reinigen.
Een daarbij gebruikt reinigingsmiddel afspoelen met schoon water. Overtollig water verwijderen.

Bij het desinfecteren zoveel vloeistof gebruiken, dat de oppervlakken gedurende de inwerkingstijd nat blijven.

1 tablet weegt 2,7 gram en bevat 1,5 gram actief chloor.

Minimale inwerkingstijd 5 minuten.

Behandelde oppervlakken of materialen die met eet- en drinkwaren en grondstoffen in contact kunnen komen dienen na de inwerkingstijd grondig met schoon water te worden nagespoeld.

Toepassingsgebieden en doseringen

1. Apparatuur en materialen, welke in contact kunnen komen met eet- en drinkwaren en grondstoffen.
   Gebruiksconcentratie: 1 tablet per 10 liter water.
2. a. Vloeren, wanden, meubilair e.d.
      gebruiksconcentratie: 1 tablet per 10 liter water
   b. Voor gebruik in ziekenhuizen en overige instellingen voor gezondheidszorg wordt het middel uitsluitend aanbevolen voor de volgende toepassingen:

	Gebruiksverdunning	Minimale inwerkingstijd
Oppervlakken (wanden, vloeren en meubilair) met uitzondering van tbc afdelingen	2 tabletten per 10 liter water	5 minuten
Oppervlakken in tbc afdelingen	5 tabletten per 5 liter water	5 minuten
Reinigingsmateriaal (dweilen e.d.)	5 tabletten per 10 liter water	30 minuten
Bedpannen en urinalen	1 tablet per 2 liter water	30 minuten
Isolettes, beademings- en narcoseapparatuur	1-2 tabletten per 10 liter water	5 minuten
Was- en beddegoed (niet van TBC-afdelingen	2 tabletten per 10 liter water	1 uur
Oppervlakken en apparatuur in keukens	2 tabletten per 10 liter water	5 minuten
Toiletten en overige sanitair	2 tabletten per 10 liter water	5 minuten

N.B.: Isolettes, beademings- en narcoseapparatuur moeten met steriel water worden nagespoeld.

3. In dierverblijfplaatsen en bijbehorende ruimten is de gebruiksconcentratie 4 tabletten per 10 liter water.
4. In transportmiddelen voor dieren is de gebruiksconcentratie 10 tabletten per 10 liter water.

Het middel is ook voor de desinfectie van transportmiddelen voor dieren volgens de Beschikking Ontsmetting Motorrijtuigen en Aanhangwagens (no. J 4510 d.d. 19 juli 1985) toegelaten.

Het middel kan ook als gecombineerd reinigings- en desinfectiemiddel gebruikt worden echter uitsluitend in combinatie met het reinigingsmiddel Suma Total D2.4 en Suma Total D2.4 conc.

Algemene werkwijze

Sterk verontreinigde oppervlakken en materialen vooraf grondig reinigen met een geschikt reinigingsmiddel en vervolgens afspoelen met schoon water.
Overtollig water verwijderen.
Licht verontreinigde oppervlakken en materialen kunnen met deze combinatie in een gang worden behandeld.

Minimale inwerkingstijd 5 minuten.

Oppervlakken die met eet- en drinkwaren en de grondstoffen hiervoor in contact kunnen komen dienen na de inwerkingstijd met schoon water grondig te worden nagespoeld.

Bereiding van de gebruiksoplossing

Meng 20 ml Suma Total D2.4 of een dosering (ca. 15 ml) Suma Total D2.4 conc. met 5 liter water.
Voeg 1 chloortablet toe en laat deze oplossen.
Voor het bestrijden van mycobacteriën (tbc afd.) 5 chloortabletten per 5 liter water gebruiken.
Voor gebruik even omroeren.

-

Waarschuwingen:

- Verneveling van het middel is niet toegestaan.
- Het middel niet in direct contact met dieren laten komen.
- Toepassing alleen met gebruik van beschermde kleding (overall), gezichtsbescherming en handschoenen.
- Ter voorkoming van nadelige effecten voor bodemorganismen dient de desinfectie van dier transportmiddelen te worden uitgevoerd op locaties met een verharde ondergrond met afvoer naar een riool met aansluiting op de RWZI.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 17 december 2010 tot verlenging van de toelating van het middel Suma Tab D4, toelatingnummer 7321 N

RISKMANAGEMENT

Contents

H.1 Introduction

This assessments concerns prolongations of authorisations of Biocidal products based on the active substances sodium dichloroisocyanurate and trichlorocyanuric acid.

The use of these products is disinfection (PT2, PT3 and PT4). In table H.1 an overview of the uses is available.

Table H.1 Overview of intended use

No.	Product	Area of use envisaged	Dosage a.s.*
		PT2	
1.	Disochlorine Chloortabletten Melquick P3-ansep Chloortabletten Suma Tab D4	Accommodations for people	0.3 g active chlorine / Liter
2.	Melquick Stafilex Chloortabletten Suma Tab D4	Areas/surfaces in hospitals and health care facilities including medical instruments, cleaning equipment, toilets, textiles etc.	1.5 g active chlorine / Liter 6 g active chlorine / Liter (TB clinics)
3.	Actisan 5L Melpool 55/G Melpool 63/G Melquick Melpool 90 Tabletten**	Therapeutic baths, private pools (not part of hotels), camping sites, recreation centres or boarding schools	0.005 g active chlorine / Liter ; 0.1 g cyanuric acid / Liter

4.	Actisan 5L	Water in casks, buckets, vases for flowers	0.03 g active chlorine per Liter
		PT3	
5.	Melquick P3-Desinfekto P3-ansep Chloortabletten Stafilex Chloortabletten Suma Tab D4	Accommodations for animals and annexes including cleaning equipment	1.6 g active chlorine / Liter
6.	Actisan 5L P3-Desinfekto P3-ansep Chloortabletten Stafilex Chloortabletten Suma Tab D4	Vehicles for animal transport	1.6 g active chlorine / Liter
		PT4	
7.	Actisan 5L Alfa plus P3-ansep Chloortabletten Stafilex Combi	Milking equipment on farms, including pipelines, tanks, machinery etc.	0.3 g active chlorine / Liter
8.	Actisan 5L Disochlorine Chloortabletten Melquick P3-Desinfekto P3-ansep Chloortabletten Stafilex Chloortabletten Stafilex Combi Suma Tab D4	Locations where food and drinks are prepared or stored – surfaces, instruments, systems, cleaning equipment with or without direct food contact.	0.8 g active chlorine / Liter

* Highest dosage selected from the different uses of the products evaluated for prolongation.
** Product contains Trichloroisocyanuric acid as active substance

H.2 Identity

n/a

H.3 Physical and chemical properties

n/a

H.4 Analytical methods for detection and identification

n/a

H.5 Efficacy

n/a

H.6 Human toxicology

Human health effects assessment active substance
Sodium dichloroisocyanurate (NaDCC or troclosene sodium) is an existing active substance, not included in Annex I of 98/8/EG. An application for inclusion is submitted, for which the United Kingdom is the Reporting Member State.

Trichlorocyanuric acid (TCCA or symclosene) is an existing active substance, not included in Annex I of 98/8/EG. An application for inclusion is submitted, for which the United Kingdom is the Reporting Member State.

For both active substances, a draft concept CA-report does not exist. Therefore, this assessment is based on the physical chemical and toxicological data as provided in a report on sodium dichloro-s-triazinetrione for the High Production Volume Chemical Challenge Program (sodium dichloro-s-triazinetrione is troclosene sodium, May 2004), published by the US Environmental Protection Agency (US EPA), and a report on tichloro-s-triazinetrione for the High Production Volume Chemical Challenge Program (tichloro-s-triazinetrione is symclosene, May 2004), published by the US Environmental Protection Agency (US EPA) and information from the Ctgb.

As both NaDCC and TCCA are chlorinated isocyanurates, and most endpoints are based on read-across studies performed with cyanuric acid, hypochlorite and chlorine, the list of endpoints for both active substances is combined (indicating which substance was used for the study).

List of Endpoints from Ctgb

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	CYA (cyanuric acid) 100%
Rate and extent of dermal absorption:	According for physical chemical properties CYA a default value of 100% should be used. However, as is known from rat studies in which **CYA** was applied dermally and poorly absorbed, a default value of **10%** will be used for risk assessment purposes. There are no data to indicate the degree of dermal absorption of hypochlorite ions. However, the potential of **hypochlorite** solutions to penetrate the skin is low given its reactivity to proteinaceous material. The absorption has therefore been assessed by assuming a default fraction of **10%** that is penetrating the skin. This is considered to be a worst-case assumption based on the indicated low potential for dermal penetration.
Distribution:	Excretion of CYA was mainly urinary.
Potential for accumulation:	No
Rate and extent of excretion:	Excretion of CYA was mainly urinary (> 95% at 5 mg/kg bw) with the remainder being faecal. For oral dosing at 500 mg/kg bw, the proportion of faecal to urinary excretion is variable at 14 – 73% urinary. In studies in humans receiving doses by the oral route, analysis showed that 100% of the ingested CYA was excreted without metabolism by the oral route within 24 hours of ingestion.
Toxicologically significant metabolite	None, chlorinated isocyanurate reduced to chloride ions and cyanuric acid.

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	NaDCC dihydrate: LD_{50} = 2094 mg/kg bw (male) LD_{50} = 1671 mg/kg bw (female) TCCA: LD_{50} = 787 mg/kg bw (male) LD_{50} = 868 mg/kg bw (female) CYA > 5000 mg/kg bw
Rat LD_{50} dermal	NaDCC dihydrate: LD_{50} > 5000 mg/kg TCCA: LD_{50} > 2000 mg/kg bw CYA > 5000 mg/kg bw
Rat LC_{50} inhalation	NaDCC dihydrate: LC_{50} > 0.27 mg/L and < 1.17 mg/L when measured gravimetrically TCCA: LC_{50} < 0.29 mg/L but > 0.09 mg/L when

	measured gravimetrically
Skin irritation	Corrosive
Eye irritation	Highly irritating
Skin sensitization (test method used and result)	Not sensitising (0/10 sensitisation rate) Guinea-pig maximisation study.

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target / critical effect	**Performed on monosodium cyanurate** Rat, male/ heart and urinary tract/lesions in early parts of 2-year study **Performed on sodium hypochlorite** Rat, decrease body weight and in specific organ weights, associated with some biochemical changes
Lowest relevant oral NOAEL / LOAEL	**Monosodium cyanurate** NOAEL 2-year combined toxicity/carcinogenicity study = 371 mg/kg bw/day (males only) **Sodium hypochlorite** NOAEL 90-day toxicity study (2 independent studies) = 46.6 mg/kg bw/day (males only)
Lowest relevant dermal NOAEL / LOAEL	NOAEC 0.1% hypochlorite solution
Lowest relevant inhalation NOAEL / LOAEL	NOAEC 0.5 ppm (1 mg/m^3) chlorine gas (monkey and human volunteer study)

Genotoxicity (Annex IIA, point 6.6)	There is no evidence of genotoxicity of CYA *in vitro* or *in vivo.*

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	No evidence of carcinogenicity in 2-year combined oral toxicity and carcinogenicity studies in the rat and mouse with monosodium cyanurate or in 24-month-whole year studies in rat with chlorine.
lowest dose with tumours	Not applicable

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	**Monosodium cyanurate** rat development/no effect on reproductive targets noted. Maternal toxicity only in teratogenicity study. Studies with **chlorine** did not show any teratogenic or reproductive effects.
Lowest relevant reproductive NOAEL / LOAEL	NOAEL maternal tox >500 mg/kg NOAEL teratogen >5000 mg/kg
Species/Developmental target / critical effect	Performed on cyanuric acid Rat/reproduction/no effect on reproductive targets noted.

Lowest relevant developmental NOAEL / LOAEL	NOAEL = 5375 ppm (470 – 500 mg/kg bw/day males only) offspring NOAEL adult toxicity (F_2 generation) = 190 mg/kg bw/day, males only

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect	No neurotoxicological effects observed in repeat dose studies. (for both cyanuric acid and chlorine studies)
Lowest relevant developmental NOAEL / LOAEL.	

Other toxicological studies (Annex IIIA, VI/XI)

n/a

Medical data (Annex IIA, point 6.9)

n/a

Summary (Annex IIA, point 6.10)	Value	Study	Safety factor
ADI (if residues in food or feed)	CYA = 3.71 mg/kg/day	2-year combined oral toxicity/carcinogenicity	100
	Chlorine = 14.4 mg/kg bw/day	US EPA IRIS	Not applicable
AEL (Operator/Worker Exposure)	CYA = 3.71 mg/kg/day	2-year combined oral toxicity/carcinogenicity	100
	Sodium hypochlorite = 0.47 mg/kg bw/day	90-days combined oral toxicity	100
Drinking water limit	Chlorine = 25.0 µg/l	Dutch drinking water guidelines	Not applicable
ARfD (acute reference dose)	CYA = 2.0 mg/kg	Rabbit teratology study	100

Data requirements active substance
No additional data requirements are identified.

6.1 Human exposure assessment active substance

6.1.1 Identification of main paths of human exposure towards active substance from its use in biocidal product

Actisan-5L
An application has been submitted for the extension of the authorisation of the biocidal product Actisan-5L (8960N). Actisan-5L are tablets used as a: private and public health area disinfectant (PT02), for surfaces, equipment, in swimming pools, and in casks/buckets/vases for flowers, veterinary hygiene biocidal product (PT03) and as a food and feed area disinfectant (PT04), containing 85% sodium dichloroisocyanurate as active substance.

The formulation Actisan-5L is for professional use

ALFA PLUS
An application has been submitted for the extension of the authorisation of the biocidal product ALFA PLUS (11482N). ALFA PLUS is a water soluble powder used as a food and feed area disinfectant (PT04), containing 9.2% sodium dichloroisocyanurate as active substance.

The formulation ALFA PLUS is for professional use.

DISOCHLORINE CHLOORTABLETTEN
An application has been submitted for the extension of the authorisation of the biocidal product DISOCHLORINE CHLOORTABLETTEN (11292N). DISOCHLORINE CHLOORTABLETTEN are tablets used as a: private and public health area disinfectant (PT02), and food and feed area disinfectant (PT04), containing 85% sodium dichloroisocyanurate as active substance.

The formulation DISOCHLORINE CHLOORTABLETTEN is for professional use.

MELPOOL 55/G
An application has been submitted for the extension of the authorisation of the biocidal product MELPOOL 55/G (10038N). MELPOOL 55/G are granules used in therapeutic baths or swimming pools for the control of micro-organisms in swimming water (PT02) and contains sodium dichloroisocyanurate (55% active chlorine) as active substance.

The formulation MELPOOL 55/G is for both professional and non-professional use.

MELPOOL 63/G
An application has been submitted for the extension of the authorisation of the biocidal product MELPOOL 63/G (8081N). MELPOOL 63/G are granules used in therapeutic baths or swimming pools for the control of micro-organisms in swimming water (PT02) and contains 100% sodium dichloroisocyanurate as active substance.

The formulation MELPOOL 63/G is for both professional and non-professional use.

MELPOOL 90 TABLETTEN
An application has been submitted for the extension of the authorisation of the biocidal product MELPOOL 90 TABLETTEN (8151N). MELPOOL 90 TABLETTEN are tablets used in therapeutic baths or swimming pools for the control of micro-organisms in swimming water (PT02) and contains 100% trichlorocyanuric acid as active substance.

The formulation MELPOOL 90 TABLETTEN is for both professional and non-professional use.

Melquick
An application has been submitted for the extension of the authorisation of the biocidal product Melquick (8813N). Melquick are tablets used as a: private and public health area disinfectant (PT02), for surfaces, equipment and in swimming pools, veterinary hygiene biocidal product (PT03) and as a food and feed area disinfectant (PT04), and contains 53% sodium dichloroisocyanurate as active substance.

The formulation Melquick is for both professional and non-professional use.

P3-ansep chloortabletten
An application has been submitted for the extension of the authorisation of the biocidal product P3-ansep chloortabletten (6377N). P3-ansep chloortabletten are tablets used as a: private and public health area disinfectant (PT02), veterinary hygiene biocidal product (PT03) and feed area disinfectant (PT04), containing 86% sodium dichloroisocyanurate as active substance.

The formulation P3-ansep chloortabletten is for professional use.

P3-DESINFEKTO
An application has been submitted for the extension of the authorisation of the biocidal product P3-

DISINFEKTO (6571N). P3-DISINFEKTO are tablets used as a: veterinary hygiene biocidal product (PT03) and feed area disinfectant (PT04), containing 41% sodium dichloroisocyanurate as active substance.

The formulation P3-DISINFEKTO is for professional use.

Stafilex Chloortabletten
An application has been submitted for the extension of the authorisation of the biocidal product Stafilex Chloortabletten (6706N). Stafilex Chloortabletten are tablets used as a: private and public health area disinfectant (PT02), for both surfaces as in swimming pools, veterinary hygiene biocidal product (PT03) and as a food and feed area disinfectant (PT04), containing 85.5% sodium dichloroisocyanurate as active substance.

The formulation Stafilex Chloortabletten is for professional use.

Stafilex Combi
An application has been submitted for the extension of the authorisation of the biocidal product Stafilex Combi (5390N). Stafilex Combi is a powder used as a food and feed area disinfectant (PT04), containing 3.4% sodium dichloroisocyanurate as active substance.

The formulation Stafilex Combi is for professional use.

Suma Tab D4
An application has been submitted for the extension of the authorisation of the biocidal product Suma Tab D4 (7321N). Suma Tab D4 are tablets used as a: private and public health area disinfectant (PT02), veterinary hygiene biocidal product (PT03) and as a food and feed area disinfectant (PT04), containing 85% sodium dichloroisocyanurate as active substance.

The formulation Suma Tab D4 is for professional use.

6.1.2 Professional exposure
The professional user can be exposed to the products during:

- Mixing and loading (including filling and maintenance of feeders of private swimming pools). The professional user can be exposed to either sodium dichloroisocyanurate (Actisan-5L, ALFA PLUS, DISOCHLORINE CHLOORTABLETTEN, MELPOOL 55/G, MELPOOL 63/G, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4) or trichlorocyanuric acid (MELPOOL 90 TABLETTEN).
- Course spraying (worst case)/dipping/mobbing/cloth (indicated is the maximum amount of cyanuric acid: **5.5 g/L (worst case),** 0.24 g/L, 0.69 g/L, 1.01 g/L, 1.38 g/L, 1.4 g/L, 1.38 g/L, 0.15 g/L and 1.38 g/L & active chlorine: **6.0 g/L (worst case),** 0.3 g/L, 0.75 g/L, 1.1 g/L, 1.5 g/L, 1.6 g/L, 1.5 g/L, 0.2 g/L and 1.5 g/L, for respectively Actisan-5L, ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4)
- Fogging is not a standard use for surfaces in public or private areas (PT02) or for veterinary accommodations/means of transport (PT03) . Furthermore, to include fogging special apparatuses are needed and additional information on how to use the product in combination with the apparatuses (which is not included for all products). Therefore, this risk assessment will not include this use for all products. As fogging induces much smaller particles, which potentially lead to much more exposure than with course spraying, which will not be assessed in this risk assessment the WG/GA needs to include the following restriction: "**Fumigation is prohibited**".

6.1.3 Non-professional exposure
The non-professional user can be exposed to products containing sodium dichloroisocyanurate (MELPOOL 55/G, MELPOOL 63/G, and Melquick) or products containing trichlorocyanuric acid (MELPOOL 90 TABLETTEN) during filling and maintenance of feeders of private swimming pools.

6.1.4 Indirect exposure as a result of use of the active substance in biocidal product

Disinfection of milking equipment or surfaces in kitchens
Actisan-5L, ALFA PLUS, P3-ansep chloortabletten, P3-DESINFEKTO, and Stafilex Combi are used for the disinfection of milking equipment. Furthermore, Actisan-5L, DISOCHLORINE

CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4 are used for the disinfection of kitchens, in which food is treated or stored. Therefore, secondary exposure of humans to cyanuric acid, HOCl and disinfection byproducts residues could occur by eating foods from kitchens and/or drinking milk from milking equipment that were treated with these products. However as it is indicated in the WG/GAs that after the treatment milking equipment and/or kitchen surfaces should be rinsed with clean (tap) water, therefore it is not expected that humans can be indirectly exposed to cyanuric acid and chlorine by eating foods from kitchens and/or drinking milk from milking equipment that were treated with these products.

Disinfections of accommodations and annexes for animals and/or means of transport for animals
Actisan-5L, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex chloortabletten and Suma Tab D4 are used for the disinfection of accommodations and annexes for animals. Furthermore, Actisan-5L, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex chloortabletten and Suma Tab D4 are also used for the disinfection of means of transport for animals. This means that livestock can be exposed to cyanuric acid, HOCl and disinfection byproducts and that humans can be exposed indirectly by consumption of animal products containing cyanuric acid, HOCl and disinfection byproducts residues. However as it is indicated in the WG/GAs that all products should be kept out of reach from animals, therefore it is not expected that humans can be indirectly exposed to cyanuric acid, HOCl and disinfection byproducts residues by the use of these products in as a animal hygiene product (PT3).

Swimming pool
Dermal, oral and inhalation exposure of the general public to cyanuric acid, HOCl and disinfection byproducts will occur during use of a swimming pool (swimming) treated with Actisan-5L, MELPOOL 55/G, MELPOOL 63/G, and MELPOOL 90 TABLETTEN.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product
The toxicity of the formulated product does not change.

6.2.2 Data requirements formulated product
No additional data requirements are identified.

6.3 Risk characterisation for human health

6.3.1 General aspects

AEL/AOELsystemic
The Plant Protection Products and Biocides Regulations (NL: Rgb) prescribes the calculation of the risk with an AEL based on allometric extrapolation in cases the existing substance is not placed on Annex I. This method takes into account the caloric demand of the species studied and results in a more specific value than the EU-AEL for which in most cases a standard factor of 100 is applied.

Cyanuric acid
The calculation of the systemic AEL for chronic is based on the lowest NOAEL of 371 mg/kg bw/day of two-year study studies with the rat. Calculations from other studies result in higher AELs.
Safety factors are used to compensate for the uncertainties, which arise, for example, from extrapolation from the tested species to humans and the differences between experimental circumstances, and to ensure that at the acceptable exposure level no adverse health effects will occur.

Used factors are:
- extrapolation rat → human on basis of caloric demand 4
- other interspecies differences: 2.5
- intraspecies differences: (professional use) 10
- biological availability via oral route: 100%*
- weight of professional operator/worker: 60 kg

* If the absorbed dose is significantly lower (<80%) than the administered dose, this is adjusted by a correction factor equal to the percentage absorption.

AELsystemic: 371 x 1 x 60 / (4 x 2.5 x 10) = 222.6 mg cyanuric acid/day

Chlorine (based on read-across van NaOCl)
The calculation of the systemic AEL for semi-chronic is based on the lowest NOAEL of 46.6 mg/kg bw/day of two subchronic oral toxicity studies with the rat. Calculations from other studies result in higher AELs.
Safety factors are used to compensate for the uncertainties, which arise, for example, from extrapolation from the tested species to humans and the differences between experimental circumstances, and to ensure that at the acceptable exposure level no adverse health effects will occur.

Used factors are:
- extrapolation rat → human on basis of caloric demand 4
- other interspecies differences: 2.5
- intraspecies differences: (professional use) 10
- extrapolation subchronic → chronic 2
- biological availability via oral route: 36.4%*
- weight of professional operator/worker: 60 kg

* If the absorbed dose is significantly lower (<80%) than the administered dose, this is adjusted by a correction factor equal to the percentage absorption.

AELsystemic: 46.6 x 0.364 x 60 / (4 x 2.5 x 10 x 2) = 5 mg sodium hypochlorite/day

5 mg sodium hypochlorite/person/day is identical to 0.08 mg sodium hypochlorite/kg bw/day. The available chlorine from NaOCl is equivalent to multiplication of the amount of NaOCl with MW (Cl_2)/MW(NaOCl) = 71/74.4 = 0.95.

AELsystemic: 5 x 0.95 = 4.8 mg available chlorine/person/day

4.8 mg available chlorine/person/day is identical to 0.08 mg available chlorine/kg bw/day.

Local effects and determination of local Acceptable Exposure Level (AEL_{local})
Due to its corrosive/irritating properties, sodium dichloroisocyanurate produces local effects after a single exposure (skin and eye irritation) and repeated exposure. Local toxic effects are caused by release of chlorinated species in response to chlorine demand.

Sodium dichloroisocyanurate produces free available chlorine, in the form of hyopchlorous acid (HOCl) as it dissolve in water. A series of rapid equilibria occur involving hypochlorous acid, hypochlorite ion, six chlorinated compounds and four non-chlorinated compounds. As the equilibria involve all of the possible chlorinated isocyanurates, the toxicity of trichloroisocyanuric acid (TCCA), sodium dichloroisocyanurate (NaDCC) and sodium dichloroisocyanurate dihydrate ($NaDCC.2H_2O$) will be virtually equivalent at the same available chlorine concentration. As the free available chlorine (in the form of HOCl) is hydrolysed by reaction with various impurities in the water it is converted into chloride ion and additional free available chlorine is released from the chlorinated isocyanurates in solution. Once all of the available chlorine has been reduced, the stable reaction products are cyanuric acid (CYA or isocyanuric acid) or its salts (e.g. sodium isocyanurate or disodium cyanurate) and chloride salts. Long-term systemic toxicity is due to the parent species, CYA, which is formed upon degradation.

The NOAECs are based on a read across to sodium hypochlorite.

Oral exposure
In the RAR of sodium hypochlorite it was concluded that a 2-year drinking water study in rats provided the overall NOAEC of 275 mg available chlorine/L drinking water, equivalent to 409 mg HOCl/L. Applying an overall assessment factor of 10 for inter- and intraspecies variability an oral limit concentration ($AEC_{local\ oral}$) of 41 mg/L is derived.

Dermal exposure
Local effects were observed in repeated dose dermal toxicity studies with NaOCl. On the basis of these studies it was concluded that the NOAEL for repeated dermal exposure to sodium hypochlorite solution was related to its cytotoxicity/irritating properties and was dependent on the concentration of the

applied solution. Therefore, skin irritation was seen as a threshold for dermal toxicity. The dermal exposure studies reflected the reversible irritant effects of sodium hypochlorite at the doses tested. In the RAR of sodium hypochlorite it was concluded that a very conservative NOAEC for repeated effects following dermal exposure to sodium hypochlorite solution is 0.1%, equal to 1 g HOCl/L. Applying an overall assessment factor of 10 for inter- and intraspecies variability a dermal limit concentration $AEC_{local\ dermal}$ of 100 mg HOCl/L is derived.

Inhalation exposure
In the RAR for sodium hypochlorite inhalation toxicity data on chlorine gas were used as a surrogate assessment of the potential effects of sodium hypochlorite aerosol. In the RAR it was concluded that the NOAEC for repeated exposure to chlorine gas in animal (12 months monkey) as well as human volunteer (single exposure) studies was 0.5 ppm, equivalent to 1 mg/m^3. This is more or less the same as the Threshold Limit Value (TLV) for chlorine (Cl_2) which is set at 1.5 mg/m^3 (for 15 min, ceiling value; Dutch Arbeidsomstandighedensbesluit). For this risk assessment an $AEL_{local\ inhalation}$ of 1.5 mg/m^3 (15 min, ceiling value) will be used.

Furthermore, household bleach is freely available for domestic uses containing 5% sodium hypochlorite

6.3.2 Professional users

The professional user can be exposed to the products during:

- Mixing and loading (including filling and maintenance of feeders of private swimming pools). The professional user can be exposed to either sodium dichloroisocyanurate (Actisan-5L, ALFA PLUS, DISOCHLORINE CHLOORTABLETTEN, MELPOOL 55/G, MELPOOL 63/G, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4) or trichlorocyanuric acid (MELPOOL 90 TABLETTEN).

  Oral exposure is deemed negligible as the user will not intently eat the product. All products are either granules or in tablet form, therefore inhalatory exposure is negligible and dermal exposure is the main route of exposure. However, as contact time to the product is very short, the dermal exposure is deemed negligible compared to the dermal exposure during application or during use of the swimming pool.

- Course spraying (worst case)/dipping/mobbing/cloth (indicated is the maximum amount of cyanuric acid: **5.5 g/L (worst case),** 0.24 g/L, 0.69 g/L, 1.01 g/L, 1.38 g/L, 1.4 g/L, 1.38 g/L, 0.15 g/L and 1.38 g/L & active chlorine: **6.0 g/L (worst case),** 0.3 g/L, 0.75 g/L, 1.1 g/L, 1.5 g/L, 1.6 g/L, 1.5 g/L, 0.2 g/L and 1.5 g/L, for respectively Actisan-5L, ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4)

  The professional user can be inhalatory and dermally exposure during course spraying to cyanuric acid: **5.5 g/L (worst case),** 0.24 g/L, 0.69 g/L, 1.01 g/L, 1.38 g/L, 1.4 g/L, 1.38 g/L, 0.15 g/L and 1.38 g/L, for respectively Actisan-5L, ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4. Oral exposure is considered to be negligible as the product is unlikely to reach the mouth directly.

  The professional user can be inhalatory and dermally exposure during course spraying to active chlorine: **6.0 g/L (worst case),** 0.3 g/L, 0.75 g/L, 1.1 g/L, 1.5 g/L, 1.6 g/L, 1.5 g/L, 0.2 g/L and 1.5 g/L, for respectively Actisan-5L, ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4. Oral exposure is considered to be negligible as the product is unlikely to reach the mouth directly.

  Systemic effects
  To calculate professional exposure to Actisan-5L (worst case for both cyanuric acid and active chlorine), the User Guidance for the Technical notes for Guidance on Human Exposure to Biocidal Products is applied. The following points have been taken into consideration:
  - Spraying Model 1 is used: mixing and loading liquids and powders in compression

sprayers or dusting applicators, and applying 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards.
- A task duration of 6 hours
- A body weight of 60 kg for the professional user

Cyanuric acid

Table T.1 Internal operator exposure to cyanuric acid and risk assessment for the use of Actisan-5L

	Route	Estimated internal exposure [a] (mg /day)	Systemic NL-AEL (mg/day)	Risk-index [b]
Manual downward/upward spraying on surfaces				
Mixing/ Loading & Application[c]	Respiratory	0.72	222.6	<0.01
	Dermal	9.01	222.6	0.04
	Total	9.73	222.6	0.04

a Internal exposure was calculated with:
- biological availability via the dermal route: 10% (default)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AEL.
c External exposure is estimated with Spraying Model 1 (TNsG).
d PPE: gloves and coverall

When used according to the WG/GA, it can be concluded that no adverse health effects are expected for the protected (gloves and coverall) professional users to cyanuric acid as a result of the application of Actisan-5L.
The same conclusion applies for ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4, as the diluted concentration of these products is lower compared to Actisan-5L.

Active chlorine

Table T.2 Internal operator exposure to active chlorine and risk assessment for the use of Actisan-5L

	Route	Estimated internal exposure [a] (mg /day)		Systemic NL-AEL (mg/day)	Risk-index [b]	
		without PPE	with PPE		without PPE	with PPE
Manual downward/upward spraying on surfaces						
Mixing/ Loading & application[c]	Respiratory	0.78	(0.78)	4.8	0.16	(0.16)
	Dermal	9.83	0.72	4.8	2.05	0.15
	Total	10.61	1.50	4.8	2.21	0.31[d]

a Internal exposure was calculated with:
- biological availability via the dermal route: 10% (default)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AEL.
c External exposure is estimated with Spraying Model 1 (TNsG).
d PPE: gloves and coverall

When used according to the WG/GA, it can be concluded that no adverse health effects are expected for the protected (gloves and coverall) professional users to active chlorine as a result of the application of Actisan-5L.
As adverse effects are expected from the unprotected professional users of Actisan-5L, the second worst case is calculated below; P3-DISINFEKTO with an maximum diluted concentration of 1.6 g/L.

Table T.3 Internal operator exposure to active chlorine and risk assessment for the use of P3-DESINFEKTO

	Route	Estimated internal exposure [a] (mg /day)	Systemic NL-AEL (mg/day)	Risk-index [b]
Manual downward/upward spraying on surfaces				
Mixing/ Loading & Application[c]	Respiratory	0.21	4.8	0.04
	Dermal	2.62	4.8	0.55
	Total	2.83	4.8	0.59

a Internal exposure was calculated with:
- biological availability via the dermal route: 10% (default)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AEL.
c External exposure is estimated with Spraying Model 1 (TNsG).
d PPE: gloves and coverall

When used according to the WG/GA, it can be concluded that no adverse health effects are expected for the unprotected professional users to active chlorine as a result of the application of P3-DESINFEKTO.
The same conclusion applies for ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, Stafilex chloortabletten, Stafilex Combi, and Suma Tab D4, as the diluted concentration of these products is lower compared to P3-DISINFEKTO.

Disinfection byproducts
As the sodium hypochlorite RAR describes that the amount of chlorinated by-products discharged (measured as absorbable organic halogens) have been shown to be typically in the order of 0.5% of the available chlorine applied.
6 g/L (Actisan-5L) x 0.5% = 0.03 g/L chlorine.

Table T.4 Internal operator exposure to disinfection byproducts and risk assessment for the use of Actisan-5L

	Route	Estimated internal exposure [a] (mg /day)	Systemic NL-AEL (mg/day)	Risk-index [b]
Manual downward/upward spraying on surfaces				
Mixing/ Loading & Application[c]	Respiratory	<0.01	4.8	<0.01
	Dermal	0.05	4.8	0.01
	Total	0.05	4.8	0.01

a Internal exposure was calculated with:
- biological availability via the dermal route: 10% (default)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AEL.
c External exposure is estimated with Spraying Model 1 (TNsG).
d PPE: gloves and coverall

When used according to the WG/GA, it can be concluded that no adverse health effects are expected for the unprotected professional users to disinfection byproducts as a result of the application of Actisan-5L.
The same conclusion applies for ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4, as the diluted concentration of these products is lower compared to Actisan-5L.

Local effects
Dermal and upper respiratory tract exposure to active chlorine: **6.0 g/L (worst case),** 0.3 g/L, 0.75 g/L, 1.1 g/L, 1.5 g/L, 1.6 g/L, 1.5 g/L, 0.2 g/L and 1.5 g/L, for respectively Actisan-5L, ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-

DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4 occurs during course spraying by the professional user.

$AEC_{local\ dermal}$ is 100 mg HOCl/L is equal to 0.01% NaOCl. As mentioned before, the available chlorine from NaOCl is equivalent to multiplication of the amount of NaOCl with MW (Cl_2)/MW(NaOCl) = 71/74.4 = 0.95. Subsequently, 0.01% NaOCl is equivalent to (0.1 g/L x 0.95 =) 0.095 g/L free chlorine. The maximum doses of all products exceed the $AEC_{local\ dermal}$.

Correct use of personal protective equipment (gloves, coverall an face visor) can reduce the dermal exposure results in a sufficient reduction of the exposure to active chlorine during the application of all products except Actisan-5L. For Actisan-5L, 2 layers of clothing (coverall + disposable coverall with hood), boots, gloves and face visor, will result in a sufficient reduction of the exposure to active chlorine during the application.

The operator can be inhalatory exposed to chlorine. $AEC_{local\ inhalation}$ is 1.5 mg/m^3 chlorine (based on a 15 min occupational health limit). The maximum inhalatory exposure to chlorine per day is: occupational health limit x breathing volume x time = 1.5 mg/m^3 x 1.25 m^3/h x 0.25 h = 0.46 mg/day. Based on the above used model (Spraying Model 1). In the worst-case scenario (Actisan-5L, maximum diluted concentration of 6.0 g/L active chlorine), the professional will be inhalatory exposed to 0.78 mg/day chlorine (Table 2). This exceeds the maximum inhalatory exposure to chlorine with a factor (0.78/0.46=) 1.7. However, as produced chloride in solution reacts more easily with other molecules than with chloride itself (which would lead to the formation of Cl_2). The model used overestimates the respiratory exposure to chlorine (a worst-case is shown, depicting the situation where all active chlorine formed, results in the formation of Cl_2). Therefore, when used according to the WG/GA, it can be concluded that no adverse health effects are expected for the unprotected professional user after inhalatory exposure to chlorine as a result of the application of Actisan-5L. The same conclusion applies for ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex chloortabletten, Stafilex Combi, and Suma Tab D4, as the diluted concentration of these products is lower compared to P3-DISINFEKTO.

On the basis of the above considerations, it can be concluded that the risk for the protected professional user is acceptable (2 layers of clothing (coverall + disposable coverall with hood), boots, gloves and face visor for Actisan-5L and coverall, gloves and face visor for ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4).

6.3.3 Non-professional users, including the general public

The non-professional user can be exposed to products containing sodium dichloroisocyanurate (MELPOOL 55/G, MELPOOL 63/G, and Melquick) or a product containing trichlorocyanuric acid (MELPOOL 90 TABLETTEN) during filling and maintenance of feeders of private swimming pools.

Oral exposure is deemed negligible as the user will not intently eat the product. All products are either granules or in tablet form, therefore inhalatory exposure is negligible and dermal exposure is the main route of exposure. However, as contact time to the product is very short, the dermal exposure is deemed negligible compared to the dermal exposure during use of the swimming pool.

On the basis of these considerations, it can be concluded that the risk for the non-professional user for all products is acceptable.

6.3.4 Indirect exposure as a result of use

Disinfection of milking equipment or surfaces in kitchens

As it is indicated in the WG/GAs that after the treatment milking equipment and/or kitchen surfaces should be rinsed with clean (tap) water, therefore it is not expected that humans can be indirectly exposed to cyanuric acid and chlorine by eating foods from kitchens and/or drinking milk from milking equipment that were treated with: Actisan-5L, ALFA PLUS, DISOCHLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi and Suma Tab D4. No residues in food and feeding stuffs are expected to arise from the use of MELPOOL

55/G, MELPOOL 63/G, and MELPOOL 90 TABLETTEN.

Disinfections of accommodations and annexes for animals and/or means of transport for animals

Actisan-5L, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex chloortabletten and Suma Tab D4 are used for the disinfection of accommodations and annexes for animals. Furthermore, Actisan-5L, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex chloortabletten and Suma Tab D4 are also used for the disinfection of means of transport for animals. This means that livestock can be exposed to cyanuric acid, HOCl and disinfection byproducts and that humans can be exposed indirectly by consumption of animal products containing cyanuric acid, HOCl and disinfection byproducts residues. However as it is indicated in the WG/GAs that all products should be kept out of reach from animals, therefore it is not expected that humans can be indirectly exposed to cyanuric acid, HOCl and disinfection byproducts residues by the use of these products in as a animal hygiene product (PT3).

Swimming pool

Dermal and oral exposure of the general public to cyanuric acid and active chlorine will occur during use of a swimming pool treated with Actisan-5L, MELPOOL 55/G, MELPOOL 63/G, and MELPOOL 90 TABLETTEN. Inhalation exposure can be considered negligible as produced chloride in solution reacts more easily with other molecules than with chloride itself (which would lead to the formation of Cl_2). It is assumed that children will spend much more time in swimming pools than adults, and accordingly will be the most exposed locally and systemically (also compared to the professional/non-professional users). Therefore the exposure as a result of use in swimming pools is only calculated for children.

Oral exposure

The following was taken into account:

- Child (4.5 years) 16.3 kg
- Chronic AEL systemic child (4.5 years)(more information, see paragraph 6.3.1) :
  - 371 x 1 x 16.3 / (4 x 2.5 x 10) = 60.5 mg cyanuric acid/day
  - 0.08 x 16.3 = 1.3 mg available chlorine/day
- Oral absorption: 100% for cyanuric acid and 36.4% for free chlorine
- From instruction of use (from all products): concentrations of cyanuric acid must not exceed a concentration of 100 mg/L and concentrations free chlorine needs to be at least 2 mg/L and at most 5 mg/L.
- Intake of 500 millilitres of swimming water.
- For a 4.5 years old child the exposed area of the body is 7090 cm^2. It is assumed that exposure occurs from a layer of 0.1 cm around the skin (based on Technical Guidance Document (2003) and Disinfectant Fact Sheet (Prud'homme de Lodder et al., 2006)). Therefore, the amount of swim water is 709 cm^3 or 0.7 L swimming water (equivalent to external exposure of 0.7 L x 100 mg/L = 70 mg cyanuric acid and 0.7 L x 5 mg/L = 3.5 mg available chlorine).

Table T.5 Chronic internal exposure to cyanuric acid and active chlorine due to use of swimming pools causing systemic effects

	Route	Internal exposure (mg /day) [a]	NL-AEL (mg/day)	Risk-index [b]
Swimming pool, cyanuric acid				
Child (4.5 years)	Oral	50	60.5	0.84
	Dermal	7	60.5	0.12
	Total	57	60.5	0.96
Swimming pool, free chlorine				
Child (4.5 years)	Oral	0.91	1.3	0.70
	Dermal	0.35	1.3	0.27
	Total	1.26	1.3	0.97
Swimming pool, disinfection byproducts				
Child (4.5 years)	Oral	<0.01	1.3	<0.01
	Dermal	<0.01	1.3	<0.01

Total	<0.01	1.3	<0.01

a Internal exposure was calculated with:
- biological availability via the oral route: 100% cyanuric acids and 36.4% sodium chlorine
- biological availability via the dermal route: 10% (default for both cyanuric acid and sodium chlorine)

b The risk-index is calculated by dividing the internal exposure by the AEL.

On the basis of the above considerations, adverse health effects after oral and dermal exposure to cyanuric acid, free chlorine and disinfection byproducts can be excluded.

Table T.6 Local external exposure to active HOCl due to use of swimming pools causing local effects

Route	external exposure (mg/L or mg/m^3)	AEC (mg/L or mg/m^3)	Risk-index [b]
Swimming pool			
Oral (mg HOCl/L)	5[a]	41 mg/L	0.12
Dermal (mg HOCl/L)	5[a]	100 mg HOCl/L	0.05
Inhalation (mg $HOCl/m^3$)	<<1[b]	0.1 mg/m^3	<<1

a Sodium chlorine concentrations is calculated from available chlorine and the multiplication with MW (NaOCl)/MW(Cl_2) = 74.4/71 = 1.05.

b based on the CAR Sodium bromide

On the basis of the above considerations, it can be concluded that the risk for the swimmer is acceptable.

6.3.5 Combined exposure

All products contain one active substance, either sodium dichloroisocyanurate or trichlorocyanuric acid. However, both active substances lead to cyanuric acid, active chlorine and disinfection byproducts. The combined toxicological effect of these three active substances has not been investigated with regard to repeated dose toxicity.

Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profile(s) based on the individual substances. After cyanuric acid, the urinary tract is affected, whereas exposure to chlorine affects the liver, spleen and blood cell status.It is therefore not expected that combined exposure to (residues of) all substances (i.e. cyanuric acid, active chlorine and disinfection byproducts) will result in an additional risk above the estimated risks based on the individual substances, when used in accordance to the WG/GA.

6.4 Overall conclusions

Based on the risk assessment, it can be concluded that the risk for the protected professional user no adverse health effects are expected.

Protection should consist of:
- 2 layers of clothing (coverall + disposable coverall with hood), boots, gloves and face visor for Actisan-5L in TB-clinics
- Coverall, gloves and face visor for Actisan-5L (in uses other than TB-clinics), ALFA PLUS, DISOCLORINE CHLOORTABLETTEN, Melquick, P3-ansep chloortabletten, P3-DESINFEKTO, Stafilex Chloortabletten, Stafilex Combi, and Suma Tab D4).

Furthermore, it can be concluded that for the swimmer no adverse health effects are expected.

Moreover, the WG/GA of all products used to disinfect surfaces in private or public areas need to include the following restriction: “fumigation is prohibited”.

6.5 Classification and labelling of the formulation concerning health

6.5.1 Proposal for the classification of the active substance

Sodium dichloroisocyanurate

Symbol:	Xn	Indication of danger: Harmful

Risk phrases	R22 R36/37	Harmful if swallowed. Irritating to eyes and respiratory system.

Trichlorocyanuric acid

Symbol:	Xn	Indication of danger: Harmful

Risk phrases	R22 R36/37	Harmful if swallowed. Irritating to eyes and respiratory system.

In Chapter 9 the complete classification and labelling for the products are mentioned.

H.7 Environment

7.1 Introduction

A prolongation of the authorisation is requested for the products Actisan-5 L; Disochlorine chloortabletten, Melquick, MELPOOL 55/G, MELPOOL 63/G, Melpool 90 Tabletten, Suma Tab D4, Stafilex Chloortabletten, Stafilex Combi, P3-Ansep Chloortabletten, P3-Desinfekto and Alfa Plus. Although the authorised products differ in uses, as a whole it concerns applications as Pt2, 3 and 4 disinfectants (see table E.1). Active substances are sodiumdichloroisocyanurate and trichlorocyanuric acid (in Melpool 90 Tabletten only).

The active substance sodiumdichloroisocyanurate consists of 2 entries for annex I inclusion: Troclosene sodium (Sodiumdichloroisocyanurate anhydrate = NaDCC) and Sodiumdihloroisocyanurate dihydrate (NaDCC-$2H_2O$), which differ only on the number of water molecules added to the active substance. It is assumed that these water molecules do not participate in the toxicity of Sodiumdihloroisocyanurate.

Trichlorocyanuric acid (TCCA or symclosene) also is an existing active substance rather similar to sodiumdichloroisocyanurate, difference is a chlorine molecule replacing the sodium molecule in sodiumdichloroisocyanurate.

Sodiumdichloroisocyanurate, sodiumdihloroisocyanurate dihydrate and trichlorocyanuric acid are chlorinated isocyanurates. Their mode of action consists in the release of chlorine and formation of cyanuric acid as carrier. Therefore most endpoints are based on read-across studies performed with cyanuric acid, hypochlorite and chlorine. It is considered acceptable to combine the list of endpoints for all three active substances.

Troclosene sodium, sodiumdihloroisocyanurate dihydrate and trichlorocyanuric acid are existing active substances, not included in Annex I of 98/8/EC. For all three active substances applications for inclusion are submitted, for which the United Kingdom is the Reporting Member State. At present a CAR for these substances does not exist.
The Board considers that sodiumdichloroisocyanurate and trichlorocyanuric acid are a bulk chemicals (C157.4; May 2005), therefore accepts publicly available data from IUCLID [2] and other data available at the CTGB [1]. Data are included for the active substance Sodiumdihloroisocyanurate (NaDCC) and its deactivated transformation product cyanuric acid (CYA). It should be noted that these data have NOT been evaluated. There are no data available for the product and this is not considered necessary.

The risk assessment for proposed applications with active substance sodiumdichloroiso-cyanurate and trichlorocyanuric acid is done in accordance with Chapter 10 of the RGB [Transition period for guideline 98/08/EC] for products based on active substances which have not been placed on Annex I of Directive 98/8/EC.
An overview of the endpoints is included in the Appendix 1 with a profile of the active substance sodiumdichloroiso-cyanurate (dihydrate), trichlorocyanuric acid, the major transformation product cyanuric acid and hypochlorite. In Appendix 2 an overview of the PNEC values is presented. In appendix 3 an overview of all ESD calculations is included.
In paragraph 7.2 a qualitative and quantitative exposure assessment, followed by a risk assessment presented in 7.3.

The products evaluated for prolongation are tablets or granulates for professional use only, with the exception of applications in pools (professional and non-professional users). The intended use is described in table E.1., see Chapter 1.

7.2 Environmental exposure assessment product

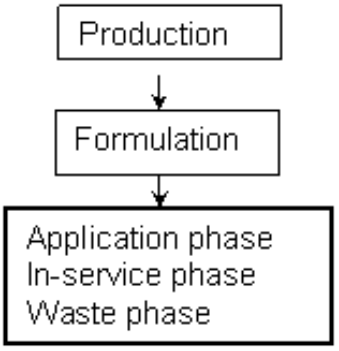
7.2.1 Chemistry and/or metabolism

The chlorinated isocyanurates hydrolyse rapidly upon addition to an aqueous environment (DT50 <1 minute) releasing free available chlorine. As the free available chlorine is consumed by reaction with organic matter and inorganic ions (chlorine demand), chloride ion is produced. The major stable degradation product is cyanuric acid (CYA).
As residual product of the oxydation process free available chlorine can be build in organic matter forming chlorinated organic micro pollutants. These chlorinated organic micro pollutants are not addressed in the environmental risk assessment, considering that these residuals are formed in small quantities (<10% of the applied chlorine).

7.2.2 Distribution in the environment

Emission routes

The following lifecycle stages are considered:



Various phases in the life cycle of a product may cause emissions and environmental exposure. Emissions from active substance production and product formulation are considered less relevant compared to emissions from the application phase, in service and waste phase of the product.

Application, in-service and waste phase

Emission to the environment during the application phase is only relevant for outdoor use at farms for the disinfection of means of transport. All other applications, including swimming pools are expected to have no emission to the environment during the application and in-service phase.

Waste phase

Emissions to the environment may occur during the waste phase when residuals of the use biocidal product are removed:

- Indoor application of the product in solutions to surfaces, materials or equipment after the prescribed contact time results in the removal of residuals to the sewer with release to the STP.
- For indoor applications at farms it is assumed that treated water with residuals of the biocidal product is removed to Manure Storage Systems. Although the emission scenarios prepared by the EU indicate that emission to the STP will occur. Release to and the consequential exposure of the STP is not considered relevant for Dutch farming as discharge of manure to the sewage system or on surface water is not permitted.
- Applications to swimming pools may result in removal of swimming water with residuals of the biocidal product to the sewer. For larger swimming pools (outdoors) and private pools, however, also direct emission to surface water occurs after drainage of the water.
- In the waste phase the treatment of water of casks, buckets, vases for flowers (4) (Actisan-5 L) will result in emission to the sewer.

Emission to the secondary compartments surface water/sediment via STP effluent depends on a number of factors such as transformation / degradation of the a.s. and its transformation products.

Emission to <u>air</u> may occur during and after application of the product due to ventilation.

Emission to soil is considered negligible for applications with emission to the STP, but relevant for applications at farms with direct emission to soil and secondary emission to soil after spreading of manure with residuals of the product. Also during the disinfection of animal transport vehicles at farms emission to soil may occur.

The foreseeable routes of entry into the environment during the application, in-service and waste phase are listed in Table E.2.

Table E.2. Foreseeable routes of entry into the environment on the basis of the use envisaged

No	Use scenario	Environmental compartments and groups of organisms exposed					
		STP	Freshwater*	Saltwater*	Soil**	Air	Birds and mammals
	PT2						
1.	Accommodations for people	++	+	-	-	(+)	(+)/-
2.	Areas/surfaces in hospitals and health care facilities including medical instruments, cleaning equipment, toilets etc.	++	+	-	-	(+)	(+)/-
3.	Therapeutic baths, private pools (not part of hotels), camping sites, recreation centres or boarding schools	++	++	-	-	(+)	(+)/-
4.	Water of casks, buckets, vases for flowers	++	+	-	-	-	(+)/-
	PT3						
5.	Accommodations for animals and annexes	-	-	-	+	(+)	(+)/-
6.	Vehicles for animal transport	-	-	-	++	(+)	(+)/-
	PT4						
7.	Milking equipment on farms, including pipelines, tanks, machinery etc.	-	-	-	+	(+)	(+)/-
8.	Locations where food and drinks are prepared or stored – surfaces, instruments, cleaning equipment with (pt4) or without food contact (pt2)	++	+	-	-	(+)	(+)/-

++ Compartment primarily exposed

+ Compartment secondarily exposed (surface water from STP discharge, vertebrates eating contaminated fish and soil after removal of manure with residuals of the product over grassland and arable land)

(+) Compartment potentially exposed

- Compartment not exposed

(+)/- The compartment is potentially exposed or not. This depends on the specific use and the characteristics of the active substance

* Including sediment

** Including groundwater, bees and non-target arthropods

It is assumed that for indoor applications with emission to the sewer or manure storage only the major transformation product cyanuric acid is relevant. The active substance and active chlorine is consumed before reaching the STP or soil.

Exposure of the aquatic and/or soil compartment to the active substance / active chlorine is relevant only for applications with outdoor use or direct emission to aquatic compartment, such as outdoor treatment of applications in swimming pools and means of animal transport.

It should be noted that the several uses may result in simultaneous emission to the STP and surface water. Therefore an accumulative risk assessment is considered relevant.

Scenarios and models used for PEC calculations
Predicted Environmental Concentrations (PEC) for indoor and outdoor applications were calculated in accordance with the scenarios from OECD Emissions Scenario Documents (ESDs) for Private area and public health area disinfectants (RIVM, 2001), Draft final ESDs for Product Type 3: Veterinary hygiene biocidal products, for Product Type 4: Disinfectants used in food and feed areas, Pt18 Insecticides for Stables and Manure Storage Systems. No EU scenario is available for the treatment of water for flowers. Instead as worst case assumption is used possible use of this product at flower auctions. Use in flower greenhouses, transporters, sellers and consumers are expected to be more diffuse, resulting in lower concentrations.

Calculations were performed with excel sheets and EUSES 2.1. Input values, calculations and results and can be found in appendix 3.
The ESD for Stables and Manure Storage Systems assumes that the emission of the active substance after application in animal housing occurs mainly via the distribution of manure (agricultural land) and waste water (STP). The fractions of the active substance that are emitted to those streams are determined by the type of pest, the type of product, the methodology of product application, and the type of housing and manure storage system.
The ESD distinguishes 18 types of animal housings. Each type has its own characteristics with respect to size, number of animals and fractions of the active substance that are emitted via manure and/or waste water. All available housing types were included in the present calculations. Considering all stable types makes it possible to define restrictive measures per animal category or stable type in case a potential risk is identified.
Manure is spread on arable land once a year and on grassland 4x a year. The PIEC after a single application of manure of land or grassland is calculated for both scenarios using an excel sheet conform the ESD on treatment of manure in stables. For grasslands, the PEC after four applications is calculated in addition to the PIEC (conform the ESD).

7.2.3 PEC in surface water, sediment and STP
Cyanuric acid has only minor sorptive characteristics (Koc 108 L/kg). Therefore it is considered that risks for the sediment are covered by the risk assessment for the aquatic compartment.

For the application in swimming water of private pools Melpool 55/G, Melpool 63/G, Melpool 90 Tabletten and Melquick direct emission to surface water may occur after drainage of the treated swimming water. For uses such as public pools, spas/hot tubs emission to the sewer and STP will occur. In table E-3 two tiers are included: tier 1 is the environmental concentration in surface water if the swimming water discharged immediately after treatment. In the second tier deactivation of the active chlorine is taken into account a 1 day deactivation period and assuming a DT50 of 4 hours. The latter value is considered realistic considering that complete drainage of a swimming pool is carried out only if the swimming water is aged and of low quality due to contaminants in the water. It is expected that in such a water active chlorine is deactivated more rapidly.

Table E-3. PECs of active chlorine and cyanuric acid for surface water, Pt 2.02 after direct emission (max. concentration 5 mg active chlorine/L and 100 mg/L cyanuric acid)

Use type	Dilution factor	Drainage	
		$PEC_{aquatic,\ intermittent}$ [mg active chlorine/L]	$PEC_{aquatic,\ intermittent}$ [mg cyanuric acid/L]
	Tier 1: Discharge immediate after treatment		
Private pools	2	2.5	50
Public pools	4	1.25	25
	Tier 2: Discharge after 3 day deactivation assuming a DT50 of 4 hours		
Private pools	2	9.54E-6	50
Public pools	4	4.77E-6	25

Scenario 2 = Van der Poel and Bakker (2002)

A direct quantitative risk assessment for the use of sodiumdichloroisocyanurate in water of casks, buckets, vases for flowers is not possible, as no information is available on the quantities used. The product can be used in flower greenhouses, auctions, flower transporters, sellers and consumers. It is expected that most emissions of treated water will occur to the sewer with connection to a STP. Worst

case application probably is the use in flower auctions. As for the emission from flower auctions the following data were derived from CBS: Discharge volume of 4 auctions per year: 3258.835 m^3/year. Assuming 200 emission days results in a discharge per auction of 4.1 m^3/day. Assuming that 90% of the water is treated results in a daily emission of 111 g cyanuric acid. In the default STP and TGD river this will result in a PEC_{sr} of 33 mg/L.

For the proposed uses in private and public health area disinfectants (PT2), Veterinary hygiene biocidal products (PT3) and food and feed area disinfectants (PT4) indirect emission to surface water will occur. For this emission route the assessment is restricted to the major transformation product cyanuric acid.

Table E-4. Use of sodium dichloroisocyanurate (expressed as kg active chlorine /d) and PECs (mg/l) of cyanuric acid for STP and surface water after indirect emission

No	Use scenario	Emission (kg/d)	PEC_{STP} (mg/L)	$PEC_{surface\ water}$ (µg/L)
	PT2			
1.	Accommodations for people (industrial and public)	0.023	0.0067	0.67
2.	Areas/surfaces in hospitals and health care facilities including medical instruments, cleaning equipment, toilets etc.	0.21	0.061	6.1
3.	Therapeutic baths, private pools (not part of hotels), camping sites, recreation centres or boarding schools	2	0.59	59
4.	Water of casks, buckets, vases for flowers	4.7	1.37	137
	PT3			
5.	Accommodations for animals and annexes	-	-	-
6.a	Vehicles for animal transport	-	-	-
	PT4			
7.	Milking equipment on farms, including pipelines, tanks, machinery etc.	0.042	0.012	1.2
8a.	Locations where food and drinks are prepared or stored – surfaces, instruments, cleaning equipment*	0.92	0.27	27
8b	Beverage industry	0.99	0.29	29
6.b	vehicles for animal transport (central disinfection)	2.62	0.76	76

*: sum of amounts used in slaughter houses and kitchens/canteens, without pre-treatment
**: Use in beverage industry

As described above all types of uses will result in emissions to the STP. The Simple treat model in EUSES 2.1 was used to derive PECs. The distribution and degree of removal of cyanuric acid in the STP is determined by the processes of biodegradation, adsorption onto sludge, removal due to sludge withdrawal and volatilisation, and was estimated using the following physical/chemical parameters (Derived from EPIwin):

- Henry's Law constant (3.79E-10 Pa*m³/mol)
- LogPow (1.95)
- biodegradability (inherently biodegradable)

7.2.4 PEC in air

See section air under risk characterisation for the environment.

7.2.5 PEC in soil and groundwater

The exposure assessment of cyanuric acid is based on the application of manure to soil and the subsequent leaching to groundwater. Additionally a soil exposure assessment is carried out for the disinfection of animal transport vehicles at farms resulting in a direct emission to soil of product residues including active chlorine and cyanuric acid.

The risk assessment of soil is based on a worst case scenario that cyanuric acid did not degrade in manure/slurry during storage. This is reasoned considering that in the Netherlands, the period of storage in certain animal housings is < 2 weeks and therefore there is a very short time period available for degradation.

The highest PIEC soil in arable land and grassland 19.8 and 27.2 µg/kg soil see Table E.5.

Table E.5. PIECsoil and groundwater for cyanuric acid for arable and grassland after treated manure application and PECsoil for active chlorine and cyanuric acid after the disinfection of a animal transport vehicle at a farm, excluding degradation.

Scenario	Category	Active chlorine	Cyanuric acid	
		Soil (mg/kg soil)	Soil (mg/kg soil)	Porewater (mg/L)
Treated manure from stables#	Arable land PIEC soil after one application	0	1.98E-02	1.63E-4
	Grassland PIECsoil after 4 applications	0	2.76E-02	2.27E-4
Animal transport vehicles	Soil after 1 disinfection treatment	15.8	13.8	-

Worst case maximum PIECsoil is directly after manure application on arable land;

The fate and behaviour profile for cyanuric acid infers that it has a high potential to reach groundwater as this compound has been shown to be mobile in soil. 4 scenarios of animal housings showed exceedance of the groundwater criteria for drinking water by a factor of 1.6 to 2.3. It should be noted, that, although not quantified, there are indications that cyanuric acid rapidly degrades under anaerobic conditions. Considering the close range to acceptability of the drinking water criterion for the 4 scenarios, fulfilment of the criterion for 14 scenarios, the uncertainties involved in the emission scenarios and the fact that biodegradation is not included in the calculations, the risk for groundwater used for the production of drinking water is considered sufficiently addressed and considered acceptable.

7.2.6 Primary and secondary poisoning of birds and mammals

The estimated log Pow of sodiumdichloroisocyanurate, trichloroisocyanuric acid, active chlorine and cyanuric acid are -0.05, not available and 1.95, respectively. Which are far below the relevant trigger value of 3 as stated in the TGD. It is concluded that the potential for sodiumdichloroisocyanurate, trichloroisocyanuric acid and its major transformation products to bio-accumulate is low and a risk of secondary poisoning does not exist.
Due the type of use of the sodiumdichloroisocyanurate and trichloroisocyanuric acid containing products primary poisoning is not expected to be of any relevance.

7.2.7 Monitoring data

Monitoring data of sodiumdichloroisocyanurate, trichloroisocyanuric acid, active chlorine and cyanuric acid in water, soil and air compartments are not available.

7.3 **Risk characterisation for the environment**

In the risk assessment presented in this chapter a comparison is made between the predicted environmental concentration (PEC), presented in the chapter above, and the Predicted No Effect Concentration (PNEC). This PNEC is derived in Appendix 2 from data available in the list of endpoints (Appendix 1). For the different uses described above PEC/PNEC ratios are calculated. If the PEC/PNEC ratio exceeds 1 then there is an unacceptable risk.

7.3.1 Aquatic compartment (incl. Sediment) and STP

STP

The proposed use may result in an emission of the active substance to the sewage system, however,

based on the rapid degradation, with a half life less than 2 minutes in activated sludge, it can be concluded that all active chlorine formed from sodiumdichloroisocyanurate or trichloroisocyanuric acid has been decomposed by reductants present in the sewage drainage system. The active chlorine will not reach the STP. Emission of the major transformation product cyanuric acid to the STP will occur after use of sodiumdichloroisocyanurate or trichloroisocyanuric acid containing products. The cyanuric acid concentration in the STP can only be derived from the amount of product used.

Table E.6. PEC/PNEC ratios of cyanuric acid for STP after emission (PNECSTP cyanuric acid = 34 mg/L)

No	Use scenario	PEC_{STP} (mg/L)	PEC/PNEC
	PT2		
1.	Accommodations for people (industrial and public)	0.0067	<0.001
2.	Areas/surfaces in hospitals and health care facilities including medical instruments, cleaning equipment, toilets etc.	0.061	0.002
3.	Therapeutic baths, private pools (not part of hotels), camping sites, recreation centres or boarding schools	0.59	0.017
4.	Water of casks, buckets, vases for flowers	1.37	0.04
	PT3		
5.	Accommodations for animals and annexes	-	-
6.a	vehicles for animal transport	-	-
	PT4		
7.	Milking equipment on farms, including pipelines, tanks, machinery etc.	0.012	<0.001
8a.	Locations where food and drinks are prepared or stored – surfaces, instruments, cleaning equipment*	0.27	0.008
8b	Beverage industry	0.45	0.008
6.b	vehicles for animal transport (central disinfection)	0.76	0.022
	Accumulative exposure		0.099

*: sum of amounts used in slaughter houses and kitchens/canteens, without pre-treatment

No unacceptable risks for micro-organisms in the STP are expected (even if all emissions are combined to one STP). Therefore the standard for micro-organisms in the STP is met for all products and applications.

Water and sediment organisms

The risk of direct emission of formed active chlorine and cyanuric acid to surface water formed after the application of sodiumdichloroisocyanurate or trichloroisocyanuric acid to swimming water is assessed in table E.7.

Table E.7 PEC/PNEC ratios of active chlorine and cyanuric acid in surface water after direct emission of treated pool water

No	Use scenario	$PEC_{surface\ water}$ (µg/L)	Acute PNEC (µg/L)	PEC/PNEC
	Discharge immediately after treatment			
	active chlorine	2500	0.3	**8333**
	cyanuric acid	50,000	6600	**7.6**
	Combination toxicity			**8340**
	Discharge after 3 days deactivation assuming a DT50 of 4 hours			
	active chlorine	0.0095	0.3	0.03
	cyanuric acid	50,000	6600	**7.6**
	Combination toxicity			**7.63**

Direct emission to surface water of treated swimming water from will result in a short term risk for aquatic organisms. Deactivation of the active chlorine will result in a lower risk, but the risk is still

unacceptable for the emission of cyanuric acid remaining in the emitted swimming water.

An overview of the risks due to indirect emission of sodiumdichloroisocyanurate or trichloroisocyanuric and its major transformation products to water and sediment organisms after discharge of wastewater through a STP is presented below.

No direct or indirect exposure of STP, surface water and sediment is expected from indoor applications of the product of the product in animal housings.

Table E-8. PEC/PNEC ratios of cyanuric acid in surface water after indirect emission via the STP (PNEC cyanuric acid = 660 µg/L).

No	Use scenario	PEC_{SW} (µg/L)	PEC/PNEC
	PT2		
1.	Accommodations for people (industrial and public)	0.67	0.001
2.	Areas/surfaces in hospitals and health care facilities including medical instruments, cleaning equipment, toilets etc.	6.1	0.009
3.	Therapeutic baths, private pools (not part of hotels), camping sites, recreation centres or boarding schools	59	0.089
4.	Water of casks, buckets, vases for flowers	137	0.21
	PT3		
5.	Accommodations for animals and annexes	-	-
6.a	Vehicles for animal transport	-	-
	PT4		
7.	Milking equipment on farms, including pipelines, tanks, machinery etc.	1.2	0.002
8a.	Locations where food and drinks are prepared or stored – surfaces, instruments, cleaning equipment*	27	0.041
8b	Beverage industry	29	0.044
6.b	Vehicles for animal transport (central disinfection)	76	0.12
	Accumulative exposure		0.52

*: sum of amounts used in slaughter houses and kitchens/canteens, without pre-treatment

No unacceptable risks for aquatic organisms in surface water are expected (even if all emissions are combined to one STP discharging to surface water). Therefore the criterion for aquatic organisms in water is met for all products and applications.

Monitoring data (surface water)
There are no data available in the Pesticide Atlas regarding the presence of sodiumdichloroiso-cyanurate or trichloroisocyanuric and major transformation products active chlorine and cyanuric acid in surface water.

All products evaluated here are on the market for more than 3 years (First product is authorised since 18-January-1991). From the general scientific knowledge collected by the Ctgb about the product, its active substance and major transformation products, the Ctgb concludes that there are no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced when used in compliance with the directions for use. The Ctgb does not expect an exceeding of the drinking water criterion when the product is used conform the Legal instructions for Use. The standards for surface water destined for the production of drinking water are met.

7.3.2 Atmosphere
Criteria for the examination of environmental risks to air are not specified by a numerical standard. Therefore, effects on air quality are only taken into account when adverse effects are predicted. Currently, the assessment of potential impacts on air quality is aimed to minimise the risk for stratospheric ozone depletion.

Within the NL framework, the following approach is used to test for ozone depletion:
The WGB admission requirements for air can be considered as generic, without a quantitative assessment. As possible effects to the air quality are qualitatively determined only, the assessment is restricted to the evaluation of the potential of the active substances regarding their potential to deplete ozone in the earth's stratosphere (ozone layer).
The FOCUS air working group developed a guidance methodology to determine the potential of a substance for ozone depletion. The following issues are considered relevant:

1. the atmospheric life time of a substance should be long enough to transport the substance to the atmosphere;
2. The substance contains one or more of the following substituents: F, Cl of Br;
3. Substances containing N and S are relevant in stratospheric ozone depletion (e.g. N_2O);

Exemplified substances are $CFCl_3$, tetrachloromethane, HCFC142b, Halon 1211 and methyl bromide with a atmospheric life time of 2 to 50 year.

As sodiumdichloroisocyanurate and trichloroisocynuric acid fulfils one of these criteria, a potential risk for ozone depletion may occur. It depends on the type of use, emission route and possible other degradation characteristics, whether ozone depletion is relevant.
A source of chlorine is from the use of sodiumdichloroisocyanurate and trichloroisocynuric acid in indoor disinfection treatments and in swimming pools. When released, this chlorine is rapidly converted to forms that dissolve in water and therefore are removed from the lower atmosphere. Such chlorine never reaches the stratosphere in significant amounts [WHO reporting}.
Therefore the proposed application of the active substances sodiumdichloroisocyanurate and trichloroisocynuric acid meet the standards for air.

7.3.3 *Terrestrial compartment*

Soil organisms

The risk assessment is targeted to the risks for soil organisms after exposure to treated manure and direct emission to soil of product residues during disinfection treatment of animal transport vehicles on farms.

Table E.9. PIECsoil and PEC/PNEC for cyanuric acid for arable and grassland after treated manure application and PECsoil and PEC/PNEC for active chlorine and cyanuric acid after the disinfection of a animal transport vehicle at a farm.

Scenario	Category	Active chlorine		Cyanuric acid	
		Soil (mg/kg soil)	PEC/PNEC	Soil (mg/kg soil)	PEC/PNEC
Treated manure from stables#	Arable land PIEC soil after one application	-	-	1.98E-02	0.001
	Grassland PIECsoil after 4 applications	-	-	2.76E-02	0.015
Animal transport vehicles	Soil after 1 disinfection treatment	15.8	**	13.8	**7.7**

Worst case scenario: maximum PIECsoil directly after manure application on arable land and grassland;
** Risk could not be determined because no PNECsoil could be derived for active chlorine.

PECsoil/PNECsoil quotients were below 1 in all 18 scenarios for transformation product cyanuric acid. Emission of residues of the products Actisan 5L, P3-Desinfekto, P3-ansep Chloortabletten, Stafilex Chloortabletten and Suma Tab D4 to soil at farms after the disinfection of animal transport vehicles, however, will result in a risk for soil organisms. Therefore risk mitigation measures are required for these products: disinfection of animal transport vehicles is restricted to locations with a hard standing with a discharge to a sewer system connected to a STP. Setting in place these risk mitigation measures, risks for soil organisms are considered acceptable for all uses.

Non-target arthropods (including bees)

The exposure of bees is considered negligible as bees are not considered to forage in animal housings or on manure treated land. Soil dwelling arthropods are considered to be covered by the risk assessment for soil organisms as cyanuric acid is assumed to have a non-specific mode of action.
All other uses as described in table E.1 are not expected to result in exposure of non-target arthropods (including bees). Therefore risks for non-target arthropods including bees are considered acceptable for all uses.

Groundwater
Assessment of the drinking water criterion takes place according to the RGB. This means that the concentration of the active substance and relevant metabolites in groundwater for the preparation of drinking water needs to be < 0.1 µg/L.
The PECgw derived using the equilibrium partitioning method from the PEC soil, estimated that for arable and grasslands, the cut off value of 0.1 µg/L would be exceeded for all animal housings and that a higher tier risk assessment was necessary.

Also PEARL predicted for cyanuric acid groundwater concentrations over 0.1 µg/L on basis of the same input parameters as EUSES. Assuming that cyanuric acid is inherently biodegradable. Considering that drinking water standard is exceeded only in 4 of the 14 scenarios by maximal 2.6, the scenarios are rather worst case and that the WHO concluded that cyanuric acid will degrade more rapidly under anaerobic conditions resulting in no risk, it is concluded that the use for the disinfection of stables fulfils the criteria for water used for the production of drinking water.

Persistence in soil
Sodiumdichloroisocyanurate and trichloroisocynurate react rapidly with organic and inorganic material in soil and will not persist. Both actives meet the standards for persistence. No soil degradation studies are available for major transformation product cyanuric acid. Cyanuric acid is considered to be not readily biodegradable in laboratory studies (OECD, 1999). However, it does biodegrade in the environment, in both soil and ambient water systems, in which it degrades to carbon dioxide and ammonia so that it does not accumulate in the environment. The standards for persistence in soil are met.

7.3.4 Non compartment specific effects relevant to the food chain
Bioconcentration and secondary poisoning
As the log K_{ow} values are < 3 for sodiumdichloroisocyanurate and cyanuric acid (-0.05 and 1.95, respectively), and as active chlorine is a reactive short living substance, a risk for bioconcentration and biomagnification is not expected (conform the biomagnification trigger value proposed for K_{ow} in the TGD).
The risk for bioconcentration and secondary poisoning in the proposed use is therefore considered not relevant. The standards for bioconcentration and secondary poisoning are met.

Primary poisoning of birds and mammals
The proposed use will not result in direct exposure of birds and mammals and thus the risk for the primary poisoning is considered acceptable.

7.4 Measures to protect the environment (risk mitigation measures)
Additional measures to protect the environment (risk mitigation measures) are required for applications related to the direct discharge of swimming water. The following mitigation measure is required for the application in swimming water of private and public pools of Melpool 55/G, Melpool 63/G, Melpool 90 Tabletten and Melquick: “To protect aquatic organisms direct discharge of the treated swimming water must be prevented”.

“Om in het water levende organismen te beschermen dient voorkomen te worden dat zwemwater of afvalwater met middelresten rechtstreeks op het oppervlaktewater wordt geloosd.”

Additional measures to protect the environment (risk mitigation measures) are required for applications related to the direct emission to soil after disinfection of animal transport vehicles at farms. The following mitigation measure is required for Actisan 5L, P3-Desinfekto, P3-ansep Chloortabletten, Stafilex Chloortabletten, Suma Tab D4: “To prevent adverse effects for soil organisms disinfection of animal transport vehicles is restricted to locations with a hard standing with a discharge to a sewer system connected to a STP”.

“Ter voorkoming van nadelige effecten voor bodemorganismen dient de desinfectie van dier transportmiddelen te worden uitgevoerd op locaties met een verharde ondergrond met afvoer naar een riool met aansluiting op de RWZI.”

7.5 Overall conclusion

It can be concluded that:

1. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate, meets the standards for aquatic and sediment organisms.
2. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate meets the standards for microorganisms in STP
3. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate meets the standards for the production of drinking water from surface water.
4. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate meets the standards for the production of drinking water from shallow groundwater and surface water.
5. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate meets the standards for the air compartment.
6. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate meets the standards for persistence in soil.
7. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate meets the standards for soil organisms.
8. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate meets the risks for non-target arthropods including bees.
9. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate meets the standards for bioconcentration
10. the proposed application of the active substance sodiumdichloroisocyanurate and trichloroisocyanurate meets the standards for primary and secondary poisoning of birds and mammals.

Based on the available data, it can be concluded that Actisan-5 L, Disochlorine Chloortabletten, Melquick, Melpool 55/G, Melpool 63/G, Melpool 90 Tabletten, Suma Tab D4, Stafilex Chloortabletten, Stafilex Combi, P3-ansep chloortabletten, P3-Desinfekto, Alfa Plus, when used in accordance with the proposed label (WG/GA) complies with the environmental standards and will not cause unacceptable effects on the environment.

Data requirements
There are no additional data required.

CONSULTED LITERATURE SOURCES

Ctgb dossier	
EUSES 2.1.1	
Pearl 3.3.3	
ESD	for PT2, 3 and 4
WHO	[3] WHO, 2007. Sodium Dichloroisocyanurate in Drinking-water - Background document for development of WHO Guidelines for Drinking-Water Quality

H.8. Conclusion

When the products Alfa Plus, Actisan-5 L, Disochlorine Chloortabletten, Melpool 55/G, Melpool 63/G, Melpool 90 Tabletten, Melquick, P3-Ansep Chloortabletten, P3-Desinfekto, Stafilex Chloortabletten, Stafilex Combi and Suma Tab D4 are used in accordance with the WG/GA no unacceptable risk is expected to human health, the person who uses the product and the environment (Art. 121 jo art. 49 first paragraph Dutch Pesticides and Biocides Act).

H.9. Classification and labelling

Actisan 5-L, 8960 N

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):

-

Symbol:	Xn, N	Indication of danger:	Harmful, Dangerous for the environment

R phrases	R22	Harmful if swallowed.
	R31	Contact with acids liberates toxic gas.
	R36/37	Irritating to eyes and respiratory system.
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S phrases	S8	Keep container dry.
	S21	When using do not smoke.
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S36/37/39b	Wear suitable protective clothing, gloves and face protection.
	S60	This material and its container must be disposed of as hazardous waste.
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Special provisions: - -
DPD-phrases
Child-resistant fastening obligatory? n/a
Tactile warning of danger obligatory? n/a

Disochlorine chloortabletten, 11292 N

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):

-

Symbol:	Xn,	Indication of danger:	Harmful,
	N		Dangerous for the environment
R phrases	R22	Harmful if swallowed.	
	R31	Contact with acids liberates toxic gas.	
	R36/37	Irritating to eyes and respiratory system.	
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	
S phrases	S8	Keep container dry.	
	S21	When using do not smoke.	
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.	
	S36/37/39b	Wear suitable protective clothing, gloves and face protection.	
	S60	This material and its container must be disposed of as hazardous waste.	
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.	

Special provisions: - -
DPD-phrases
Child-resistant fastening obligatory? n/a
Tactile warning of danger obligatory? n/a

MELQUICK 8813 N

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):

-

Symbol:	Xn,	Indication of danger:	Harmful,
	N		Dangerous for the environment
	O		Oxidizing
R phrases	R8	Contact with combustible material may cause fire.	
	R22	Harmful if swallowed.	
	R31	Contact with acids liberates toxic gas.	
	R36/37	Irritating to eyes and respiratory system.	
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse	

		effects in the aquatic environment.
S phrases	S8	Keep container dry.
	S21	When using do not smoke.
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S36/37/39b	Wear suitable protective clothing, gloves and face protection.
	S60	This material and its container must be disposed of as hazardous waste.
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Special provisions: - -
DPD-phrases
Child-resistant fastening obligatory? n/a
Tactile warning of danger obligatory? n/a

P3-ansep chloortabletten, 6377 N

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):

-

Symbol:	Xn,	Indication of danger:	Harmful,
	N		Dangerous for the environment
	O		Oxidizing
R phrases	R8	Contact with combustible material may cause fire.	
	R22	Harmful if swallowed.	
	R31	Contact with acids liberates toxic gas.	
	R36/37	Irritating to eyes and respiratory system.	
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	

S phrases	S8	Keep container dry.
	S21	When using do not smoke.
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S36/37/39b	Wear suitable protective clothing, gloves and face protection.
	S60	This material and its container must be disposed of as hazardous waste.
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Special provisions: - -
DPD-phrases
Child-resistant fastening obligatory? n/a
Tactile warning of danger obligatory? n/a

P3-desinfecto, 6571 N

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):

-

Symbol:	Xn,	Indication of danger:	Harmful,
	N,		Dangerous for the environment
	O		Oxidizing
R phrases	R8	Contact with combustible material may cause fire.	
	R22	Harmful if swallowed.	
	R31	Contact with acids liberates toxic gas.	
	R37/38	Irritating to respiratory system and skin.	
	R41	Risk of serious damage to eyes.	
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	

S phrases	S8	Keep container dry.
	S21	When using do not smoke.
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S36/37/39b	Wear suitable protective clothing, gloves and face protection.
	S60	This material and its container must be disposed of as hazardous waste.
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Special provisions: - -
DPD-phrases
Child-resistant fastening obligatory? n/a
Tactile warning of danger obligatory? n/a

Stafilex Chloortabletten, 6706 N

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):

-

Symbol:	Xn, N	Indication of danger:	Harmful, Dangerous for the environment

R phrases	R22	Harmful if swallowed.
	R31	Contact with acids liberates toxic gas.
	R36/37	Irritating to eyes and respiratory system.
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S phrases	S8	Keep container dry.
	S21	When using do not smoke.
	S22/23-NL	Do not breath dust and spray.
	S36/37/39b	Wear suitable protective clothing, gloves and face protection.
	S60	This material and its container must be disposed of as hazardous waste.
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Special provisions: - -
DPD-phrases
Child-resistant fastening obligatory? n/a
Tactile warning of danger obligatory? n/a

Suma Tab D4, 7321 N

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):

-

Symbol:	Xn, N	Indication of danger:	Harmful, Dangerous for the environment

R phrases	R22	Harmful if swallowed.
	R31	Contact with acids liberates toxic gas.
	R36/37	Irritating to eyes and respiratory system.
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S phrases	S8	Keep container dry.
	S21	When using do not smoke.
	S22/23-NL	Do not breath dust and spray.
	S36/37/39b	Wear suitable protective clothing, gloves and face protection.
		This material and its container must be disposed of as

S60	hazardous waste.
S61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Special provisions:	-	-
DPD-phrases		
Child-resistant fastening obligatory?		n/a
Tactile warning of danger obligatory?		n/a

The current classification and labelling, which are prepared in conformity with Directive 1999/45/EC, can be maintained for the products:
Alfa Plus, Melpool 55/G, Melpool 63/G, Stafilex Combi and Melpool 90 Tabletten.

H.10 References

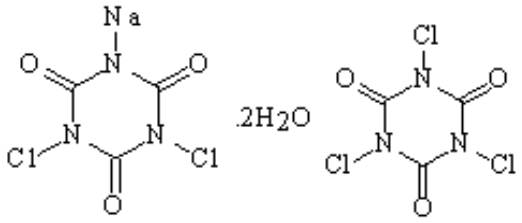
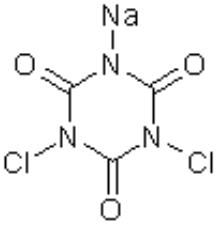
No references are available.

Appendix 1 List of Endpoints sodiumdichloroisocyanurate and trichloroisocyanurate

This List of endpoints contains studies not evaluated by the CTGB as these are currently under assessment as part of the EU BPD Annex I inclusion process.

Profile of active substance

Identity

Chemical name (CA)	Troclosene sodium = Sodiumdihloroisocyanurate anhydrate (NaDCC) Sodiumdihloroisocyanurate dihydrate (NaDCC-2H_2O) Trichloroisocyanuric acid (TCCA),
CAS No	2893-78-9 51580-86-0 87-90-1
Molecular formula	C3C12N3O3.Na C3Cl2N3O3.2H2O.Na C3Cl3N3O3
Molecular mass	Troclosene sodium: 219.95 Sodium dichloroisocyanurate dihydrate: 255.98 TCCA 232.41
Structural formula	Troclosene sodium TCCA  Sodium dichloroisocyanurate dihydrate  CYA (transformation product):

Physical and chemical properties

Appearance (state purity)	White granular solid with chlorine odour
Specific gravity	Sodium dichloroisocyanurate dihydrate: 1.97 g/mL at 25°C CYA: 1.75 g/mL
Vapour pressure (in Pa, state temperature)	< 0.06 Pa at 20 ºC
Henry's law constant	5.28 E-05 atm-m^3/mole fraction (calculated) *5.35 Pa-m^3/mole* *TCCA <0.002 Pa at 20°C (equivalent to OECD 104)*
Solubility in water (g/l or mg/l, state temperature)	The active substance hydrolyses rapidly upon addition to water. The results of the study therefore reflect the hydrolysis reaction and the resultant solubility of the hydrolysis products. Troclosene sodium: 15000 mg/L (10°C) 20000 mg/L (20°C) 28000 mg/L (30°C)
	Sodium dichloroisocyanurate dihydrate: 17000 mg/L (10°C) 22500 mg/L (10°C) 31000 mg/L (10°C)
Partition coefficient (log P_{OW})	Log Pow = -0.0556 TCCA: Log Pow = 0.94 The substance is a salt which hydrolyses rapidly in water ($t_{1/2}$ < 1 second) forming polar products which are insoluble in octanol and soluble in water, which suggests that the Pow would be very low. The active substance reacts with octanol..

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Chlorinated isocyanurate t½ < 1 minute CYA t½ > 30 days at 25% at all environmentally relevant pH *0% after 30 days [2]*
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	CYA t½ > 30 days at 25°C in water
Readily biodegradable (yes/no)	TCCA or NaDCC – No, inherently biodegradable CYA – No. CYA degrades rapidly under anaerobic conditions (soils, sediments) or under conditions of low dissolved oxygen. (100% degradation in activated sludge (2.5 mg/l O_2) in 8 hours)
Biodegradation in seawater	Not applicable
Non-extractable residues	Not applicable

Distribution in water / sediment systems (active substance)	TCCA or NaDCC undergoes rapid hydrolysis to form available chlorine in the form of HOCl and cyanuric acid.
Distribution in water / sediment systems (metabolites)	Available chlorine will be rapidly reduced by organic matter, the stable reaction products are CYA or its salts and chloride salts. CYA degrades under a wide variety of natural conditions, and particularly well in systems of either low or zero dissolved oxygen, such as anaerobic activated sludge and sewage, soils, mud's, etc. The overall degradation reaction is hydrolysis, initially to carbon dioxide and ammonia. Since no net oxidation occurs, CYA exerts no primary biological oxygen demand. However, eventual nitrification of the ammonia would exert its usual biological oxygen demand. Organisms degrading CYA under anaerobic conditions do not require acclimatisation. In highly aerobic media, CYA resists biodegradation.

Route and rate of degradation in soil

Mineralization (aerobic)	Not performed – not applicable to the proposed product types.
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Not performed
Field studies (state location, range or median with number of measurements)	Not performed
Anaerobic degradation	CYA degrades readily under a wide variety of natural conditions, and particularly well in systems of either low or zero dissolved oxygen, such as anaerobic activated sludge and sewage, soils, muds (Saldick J (1974) 100% degradation in farm soil in 23 days.
Soil photolysis	No data available
Non-extractable residues	No data available
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	No data available
Soil accumulation and plateau concentration	CYA degrades readily under a wide variety of natural conditions, and particularly well in systems of either low or zero dissolved oxygen, such as anaerobic activated sludge and sewage, soils, mud's, etc. The overall degradation reaction is hydrolysis, initially to carbon dioxide and ammonia. Since no net oxidation occurs, CYA exerts no primary biological oxygen demand. However, eventual nitrification of the ammonia would exert its usual biological oxygen demand. Organisms degrading CYA under anaerobic conditions do not require acclimatisation.

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Performed on CYA K_d = 0.114 – 0.622 K_{oc} = 8 – 150 No. TCCA or NaDCC is rapidly reduced by reaction with inorganic species in soil. Mobility of CYA decreases with decreasing organic matter.

Fate and behaviour in air

Direct photolysis in air	No absorbance in the UV at < 290 nm Indirect photolysis with OH radicals (TCCA/NaDCC/CYA) = 43 hours with an overall OH rate constant of 3.00 E-12 cm^3/molecule-sec (calculated, EPIWIN v 3.12)
Quantum yield of direct photolysis	No data available
Photo-oxidative degradation in air	Latitude: ..... Season: ..... DT_{50}.....
Volatilization	The active substance is not volatile; however, available chlorine and chloride will be released when the active substance is in the aqueous environment, therefore small emissions of chlorine compounds (HOCl and chloramines) to the air compartment would be expected during use of the substance. These compounds are very short-lived due to their high reactivity, therefore there is insignificant risk. The lifetime of HOCl in the stratosphere under photolysis conditions is at most 30 min. The amount of chloride released from use of these compounds is insignificant compared to natural sources.

Monitoring data, if available

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	Monitoring data from a single manufacturing site has shown that the actual exposure is 0.1 ppm (0.145 mg/m^3) chlorine.

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group) CYA

Species	Time-scale	Endpoint	Toxicity
Fish			
Salmo gairdneri	96h	LC_{50}	>2100 mg/L of CYA measured/nominal
Salmo gairdneri	21 days	NOEC	= 756 mg/L of CYA measured/nominal
Invertebrates			
Daphnia magna	48 hr	EC_{50}	> 1000 mg/L of CYA measured/nominal
Daphnia magna	21 day	NOEC	= 121 mg/L of CYA measured/nominal
Algae			
Selenastrum capricornutum	96 hr	EC_{50}	= 655 mg/L of CYA measured/nominal
N. pelliculosa	96 h	NOEC	= 945 mg/L of CYA measured/nominal
Microorganisms			

Activated sludge, predominantly domestic sewage	3 h	EC_{50}	= 3402 mg/L of CYA

Toxicity data for aquatic species (most sensitive species of each group) NaDCC

Species	Time-scale	Endpoint	Toxicity
Fish			
Salmo gairdneri	*96 h*	*LC_{50}*	*0.22 mg/L [2]*
Invertebrates			
Daphnia magna	48 hr	EC_{50}	0.196 *µg/L* of NaDCC anhydrous nominal *[2]*
Daphnia magna	*48 hr*	*EC_{50}*	*0.28 mg/L [2]*
Algae			
No data available			
Microorganisms			
No data available			

Toxicity data for aquatic species (most sensitive species of each group) Trichloroisocyanuric acid (TCCA)

Species	Time-scale	Endpoint	Toxicity
Fish			
Salmo gairdneri	96h	LC_{50}	0.24 mg/L of TCCA nominal
Lepomis macrochirus	96h	LC_{50}	> 0.23 mg/L of TCCA nominal
Oryzias latipes	96h	LC50	0.3 mg/L TCCA [2]
Invertebrates			
Daphnia magna	48 hr	NOEC	= 0.21 mg/L of TCCA measured/nominal
Daphnia magna	48 hr	NOEC	0.17 of TCCA measured/nominal
Daphnia magna	48h	EC50	0.21 mg/L TCCA [2]
Algae			
Chlorella pyrenoidosa. Euglena gracilis, Scenedesmus obligauus	96 hr	EC_{50}	= 655 mg/L of CYA measured/nominal 0.5 mg/L TCCA nominal
Microorganisms			
Activated sludge, predominantly domestic sewage	3 h	EC_{50}	= 59 mg/L of TCCA

Effects on sediment dwelling organisms

Acute toxicity to	CYA is not toxic to chironomid. NOEC = 756 mg/kg wwt

Effects on earthworms or other soil non-target organisms

Acute toxicity to ……	CYA is not toxic to earthworms. NOEC = 756 mg/kg wwt

Reproductive toxicity to ……	No data available

Effects on soil micro-organisms

Nitrogen mineralization	No data available
Carbon mineralization	No data available

Effects on terrestrial vertebrates

Acute toxicity to mammals	NaDCC dihydrate: LD50 = 2094 mg/kg bw (male) LD50 = 1671 mg/kg bw (female) TCCA: LD50 = 787 mg/kg bw (male) CYA > 5000 mg/kg bw
Reproductive toxicity to mammals	Performed on cyanuric acid NOEL = 5375 ppm (470 – 500 mg/kg bw/day males only) offspring NOAEL adult toxicity (F2 generation) = 190 mg/kg bw/day, males only
Acute toxicity to birds	No data available
Dietary toxicity to birds	NaDCC is not toxic to birds. LD50 = 1766 mg/kg TCCA is not toxic to birds. LD50 = 1630 mg/kg
Reproductive toxicity to birds	No data available

Effects on honeybees

Acute oral toxicity	No data available
Acute contact toxicity	No data available

Effects on other beneficial arthropods

Acute oral toxicity	No data available
Acute contact toxicity	No data available
Acute toxicity to ……..	No data available

Bioconcentration

Bioconcentration factor (BCF)	The chlorinated isocyanurates react rapidly in aqueous solutions releasing free available chlorine, therefore the Log Pow of any of the chlorinated isocyanurates are expected to be low. The calculated Log BCF for NaDCC is 0.286 (BCF = 1.932). If absorbed, the available chlorine will readily react with proteins in tissue to form oxidized proteins, chloride ion and CYA. The measured Log Pow of the CYA is -1.31 giving a calculated Log BCF of 0.500 (BCF = 3.162). Therefore, there is no potential for bioaccumulation.
Depuration time (DT_{50}) (DT_{90})	Not measured
Level of metabolites (%) in organisms accounting for > 10 % of residues	None

Input parameters for cyanuric acid in EUSES and PEARL

Parameter	Input	Unit	d/s/o*
Molecular weight	**128**	**g/mol**	**s**
Melting point	**193**	**^{o}C**	**s**
Boiling point	**458**	**^{o}C**	**s**
Vapour pressure	**5.87E-9**	**Pa at 25 ^{o}C**	**s**
Water solubility	**2E+03**		**s**

		Mg/L at 25 ^{o}C	
Octanol water partitioning coefficient	**1.95**	**L/kg**	**s**
Koc	**108**	**L/kg**	**o**
Henry's law constant	**3.79E-10**	**Pa.m^{3}.mol^{-1}**	**o**
Biodegradation	**Inherently biodegradable DT50 300**	**-[d] at 12^{o}C**	**s**

d=default; s=set; o=calculated.

Active chlorine

Toxicity for aquatic organisms:

Ecotoxicological data free available / active chlorine (FAC) are mainly available from open literature. In de RAR of RMS Italy (November 2007) an overview of the endpoints available in the open literature concerning the toxicity to aquatic organisms, see the table presend below.

SUMMARY OF ECOTOXICITY DATA SELECTED FOR THE DETERMINATION OF THE PNEC FOR FRESHWATER ORGANISMS

SHORT-TERM TOXICITY				
	Valid data		**Supportive information**	
	Endpoint	**Study Details/Reference**	**Endpoint**	**Study Details/Reference**
Fish	-		96-168h LC50 = 60-33 µg TRC/l >30 - > 16.5 µg FAC/l (FAC > 50%)	(intermittent exposure, 40'x3 times/d) (Heath, 1977, 1978)
Crustaceans (Ceriodaphnia)	24h LC50 = 5 µg FAC*/l (rated 2)	Taylor, 1993		
Algae	-		-	
LONG –TERM TOXICITY				
	Valid data		**Supportive information**	
Fish	-		134d NOEC = 5 µg TRC/l No FAC specified.	growth (field study) (Hermanutz et al., 1990)
Crustaceans	-		-	
Mollusks (bivalves)	-		36d 100% mortality	50 µg TRC/l
Algae	7d NOEC = 3 µg TRC/l (rated 2) 2.1 µg FAC/l (FAC 73%)	Biomass (microcosm study) (Cairns et al., 1990)	28d EC50 = 2.1 µg TRC/l 2.1 µg FAC/l (FAC (100%)	Biomass (microcosm study) (Pratt et al., 1988)
Mesocosm study			24d NOEC = 1.5 µg TRC/l (rated 2) 1.5 µg FAC/l (FAC 100%)	(zooplankton density) (Pratt et al., 1988)

FAC = (free available chlorine)

TRC = total residual chlorine

**FAC as HOCl*

rates: 1 = valid

2 = valid with restriction

s = supportive information

RIZA determined an ad hoc chronic MTR of 0.3 µg active chlorine /L, which is in line with the available data presented above and used in the risk assessment.

[3] **Fate of sodium dichloroisocyanurate in (drinking) water**

When added to water, NaDCC (anhydrous or dihydrate) rapidly hydrolyses to release Free Available Chlorine FAC and establish a complex series of equilibria involving six chlorinated and four non-chlorinated isocyanurates. These equilibria are established on the order of seconds (Matte et al., 1989). The concentration of each species depends on the concentrations of total available chlorine (TAC = FAC plus "reservoir" chlorine, e.g. as DCC−) and total isocyanurates, the pH and the values of the equilibrium constants (dependent on temperature and ionic strength). "Reservoir" chlorine refers to the bound chlorine of the various chloroisocyanurates. The latter function as reservoirs of rapidly released FAC, as FAC is depleted. Thus, if hypochlorous acid is consumed by reaction with organic material (oxidation), chloroisocyanurates will rapidly dissociate to release more hypochlorous acid.

The FAC for anhydrous NaDCC (commercial product) is 62–64%, and the dihydrate has 55–56% FAC; the FAC for elemental chlorine is 100% (Pinto & Rohrig, 2003).

Therefore, development of 1 mg of FAC per litre, typical for drinking-water treatment, requires approximately 1.6 mg of anhydrous NaDCC per litre and approximately 1.8 mg/l for the dihydrate. The distribution of the various chemical species in aqueous solutions of NaDCC can be calculated from their hydrolysis and acid dissociation constants. As an example (OxyChem, 1997), dissolution of NaDCC to provide 1.0 mg of TAC per litre, at pH 7.0, gives the following: 48.1% TAC from hypochlorous acid, 26.8% TAC from monochlorocyanurate, 11.8% TAC from dichlorocyanurate, 12.8% TAC from hypochlorite and less than 1% from other chlorocyanurates and chlorocyanuric acids.

In normal batch-type use of NaDCC, oxidative and microbiocidal demand will consume FAC until all available chlorine has been reduced, leaving only nonchlorinated isocyanurates/cyanurate (e.g. cyanuric acid). As long as NaDCC is added to water to maintain a certain level of TAC or FAC, however, the various cyanurates will be present at levels dependent on the properties of the water (i.e. pH, temperature, etc.) (Kuznesof, 2003).

Cyanuric acid is considered to be not readily biodegradable in laboratory studies (OECD, 1999). However, it does biodegrade in the environment, in both soil and ambient water systems, in which it degrades to carbon dioxide and ammonia so that it does not accumulate in the environment (Saldick, 1975; Jessee et al., 1983; de Souza et al., 1998; Ghosh & Philip, 2006; Satsuma, 2006; Shiomi et al., 2006).

Appendix 2. PNEC derivation

The RGB requires that the environmental risk is assessed on basis of Predicted No Effect Concentrations (PNEC), which determined in line with the Technical Guidance document (version 2003 chapter 3). PNEC values for the different compartments are derived from ecotoxicity data and applying assessment factors. Depending on the type of data (acute or chronic) and number of data a certain assessment factor is selected.

Aquatic organisms

Table 1a. NaDCC and CYA - selected data freshwater species

Taxonomic groups and species	Acute L(E)C50 (mg/l) NaDCC	Acute L(E)C50 (mg/l) CYA
Algae		
Selenastrum capricornutum	No data available	655 mg/L of CYA
Crustacea		
Daphnia magna	0.196 µg/L	> 1000 mg/L of CYA
Pisces		
Salmo gairdneri	0.22	756 mg/L of CYA

Acute toxicity endpoints for the active substance NaDCC are available only for crustaceans and fish. Thus no PNEC could be derived. A complete set of ecotoxicity data is available for the transformation product cyanuric acid (CYA).

Table 1b PNEC derivation for surface water

Starting point	Assessment factor	LC50 mg a.s./L	PNEC
NaDCC			
Acute toxicity to Daphnia	-	-	Insufficient data to determine*
TCCA			
Acute toxicity to *Daphnia magna*	Acute: 100 Chronic: 1000	0.21	Acute: 2.1 µg/L Chronic: 0.21 µg/L
CYA			

Acute toxicity to algae	Acute: 100 Chronic: 1000	655	Acute: 6.6 mg/L Chronic: 0.66 mg/L
Active chlorine			
Adhoc MTR			0.3 µg/L

* ecotoxicity data on algae are missing. Additionally in the literature contradicting data on the toxicity of NaDCC to Daphnia are available.

PNECstp
Data concerning the toxicity of CYA to active sludge are available. No data are available concerning the toxicity of NaDCC

Table 2 PNEC derivation for STP

Starting point	Assessment factor	EC50 mg a.s./L	PNEC
NaDCC			
Active sludge			Insufficient data to derive PNEC
TCCA			
Active sludge	100	59	0.59 mg a.s./L
CYA			
Active sludge	100	3402	34 mg/L

Soil organisms
Studies in which the test organisms were exposed to NaDCC and TCCA via soil are not available. One acute toxicity earthworm test result is available for cyanuric acid with a NOEC of 756 mg/kg wwt.

PNEC soil:
Insufficient data is available to derive a PNEC soil for NaDCC and TCCA. One acute toxicity study with earthworms is available for CYA with a NOEC of 756 mg/kg ww, which is insufficient for a reliable PNECsoil. Therefore for transformation product CYA a PNECsoil is determined on basis of equilibrium partitioning.

Table 3 PNEC derivation for the soil

Starting point	Assessment factor	$K_{soil\text{-}water}$	PNEC
NaDCC			
Not determined	-	No Koc available	Not calculated
CYA			
$PNEC_{aquatic}$ = 0.66 mg / L	1	4.7	1.8 mg/kg ww 2.0 mg/kg dw

Air
No methodology is available to derive a PNEC for air. The air compartment is assessed qualitatively on basis of intrinsic properties.

Birds and mammals

Table 4 PNEC derivation for birds and mammals

Starting point	Assessment factor	Lowest test LD50	PNEC
NaDCC			
Dietary LD50 bird	3000	1766 mg/kg bw	0.59 mg/kg bw
TCCA			
Dietary LD50 bird	3000	1630 mg/kg bw	0.54 mg/kg bw
CYA			
Chronic NOAEL rat	30	190 mg/kg bw/day,	6.3 mg a.s./kg bw

Appendix 3. Calculation sheets Environment

Results of the ESD calculations are presented in the tables below. Input data for the active susbstance

and/or cyanuric acid are derived from the PGB

No.	Area of use envisaged	Dosage a.s.	Dosage Cyanuric acid
	PT2		
1.	Accommodations for people	0.3 g active chlorine / Liter	0.3 g/L
2.	Areas/surfaces in hospitals and health care facilities including medical instruments, cleaning equipment, toilets, textiles etc.	1.5 g active chlorine / Liter 6 g active chlorine / Liter (TB clinics)	5.5 g/L
3.	Therapeutic baths, private pools (not part of hotels), camping sites, recreation centres or boarding schools	0.005 g active chlorine / Liter;	0.1 g / L
4.	Water in casks, buckets, vases for flowers	0.03 g active chlorine per Liter	0.03 g/L
	PT3		
5.	Accommodations for animals and annexes including cleaning equipment	1.6 g active chlorine / Liter	1.4 g/L
6.	Vehicles for animal transport a. disinfection at farms b. centralised disinfection	1.6 g active chlorine / Liter	1.4 g/L
	PT4		
7.	Milking equipment on farms, including pipelines, tanks, machinery etc.	0.3 g active chlorine / Liter	0.24 g/L
8a.	Locations where food and drinks are prepared or stored – surfaces, instruments, systems, cleaning equipment	0.8 g active chlorine / Liter	0.72 g/L
8b	Beverage industry	0.8 g active chlorine / Liter	0.72 g/L

1. Disinfection of surfaces in industrial, public areas PT2:

Calculation for cyanuric acid

Table 1. Disinfection of surfaces in industrial, public areas PT2:

- spraying with trigger spray
- wiping with mop and bucket (disinfection of floors)
- wiping with cloth and bucket (disinfection of other surfaces than floors)

Variable/parameter	Unit	Symbol	S/D/O/P	Value	Remark
Fraction released to waste water for “sanitary purpose”	[--]	Fsan,water	D	0.55	ESD, table 2.13
Fraction released to waste water for “brushes”	[--]	Fobj,water	D	0.95	ESD, Table 2.13
Concentration at which the active substance is used	[kg/L]	Csan/ Cobj	S	0.0003	
Amount of water with active substance for “sanitary purpose”	[L]	Qwater_san	S	50	25 L is default, the value used concerns the combined use of the product in industrial and public areas as both may emit to the same STP
Amount of water with active substance for “brushes”	[L]	Qwater_obj	S	50	Idem
Output: Elocalwater san= Emission rate to waste water, sanitary purpose [kg/d] = disinfection of floors Elocalwater obf= Emission rate to waste water, brushes [kg/d] = disinfection of surfaces other than floors Elocalwater san+obj= Emission rate to waste water, sanitary purpose + brushes [kg/d] = spray application					
Calculation: Elocalwater san = Qwater_san * Csan * Fsan,water Elocalwater obj = Qwater_obj * Cobj * Fobj,water Elocalwater san+obj = (Qwater_san * Csan * Fsan,water) + (Qwater_obj *				0.008 kg/d 0.014 kg/d 0.023 kg/d	

Cobj * Fobj,water)	

Table 2.1 Disinfection of surfaces in health care areas – PT2

- spraying with trigger spray
- wiping with mop and bucket (disinfection of floors)
- wiping with cloth and bucket (disinfection of other surfaces than floors)

				CYA	
Variable/parameter	Unit	Symbol	S/D/O/P	Value	Remark
Fraction released to waste water for "sanitary purpose"	[--]	Fsan,water	D	0.55	ESD, table 2.13
Fraction released to waste water for "brushes"	[--]	Fobj,water	D	0.95	ESD, Table 2.13
Concentration at which the active substance is used	[kg/L]	Csan/ Cobj	S	0.0055	
Amount of water with active substance for "sanitary purpose"	[L]	Qwater_san	D	25	
Amount of water with active substance for "brushes"	[L]	Qwater_obj	D	25	
Output: Elocalwater san= Emission rate to waste water, sanitary purpose [kg/d] = disinfection of floors Elocalwater obf= Emission rate to waste water, brushes [kg/d] = disinfection of surfaces other than floors Elocalwater san+obj= Emission rate to waste water, sanitary purpose + brushes [kg/d] = spray application					
Calculation: Elocalwater san = Qwater_san * Csan * Fsan,water Elocalwater obj = Qwater_obj * Cobj * Fobj,water Elocalwater san+obj = (Qwater_san * Csan * Fsan,water) + (Qwater_obj * Cobj * Fobj,water)				0.076 kg/d 0.131 kg/d 0.206 kg/d	

Table 2.2 Emission scenario for calculating the release of disinfectants used in hospitals for disinfection of scopes and other articles in washers/disinfectors

Variable/parameter (unit)	Unit	Symbol	S/D/O/P	Value	
Input:					
A + B) Replacement + Once-through					
Working concentration of active ingrediënt (g.1-1)	g/L	Cproc	S	0.3	Cyanuric acid
Maximum number of washers / disinfectors		$Nmax_{mach}$	D	3	
Volume of solution in machine (1)		Vproc			
A) Replacement	L		D	100	
B) Once-through	L		D	10	
A) Replacement					
Replacement interval (d)		$Tint_{repl}$	D	14	
Fraction carry-over (-)		Fcarry_over	D	0.015	
Rate constant for chemical conversion (d-1)		$kdeg_{disinf}$	S/D	0	
Output: $Elocal3_{;Water}$ = Maximum emission rate to water (kg.d-1)					
Intermediate calculations: *A) Replacement* Concentration at day of replacement due to carry-over (mg.1^{-1}) $Cproc_{carry\_over}$ = Cproc *10^3 / (1 + Fcarryover)$^{Tint\text{-}appl}$ Concentration at day of replacement including conversion (mg.-1) $Cproc_{repl}$ = $Cproc_{carry\_over}$ * $e^{-kdeg\ disinf\ *\ Tint\ repl}$				243.555 243.555	mg/L mg/L
End calculations: *A) Replacement* $Elocal_{3;Water}$ = $Nmax_{mach}$ * Vproc * $Cproc_{repl}$ * 10^{-6} *B) Once-through*				0.07307	kg/d

$Elocal_{3;water} = Nmax_{mach} * Vproc * Cproc * 10^{-6}$			0.00731	kg/d

1) For 'replacement' assumption that replacement occurs on the same day

2) Zero by default if no data are supplied

3) The subscript "3" refers to the stage of processing in conformity with EUSES 1.0 and USES 3.0

3. Disinfection swimming pools – PT2

Table 4.1 Discharge of swimming water by public swimming pools into the sewage system for chronic situation

Variable/parameter (unit)		Symbol	**Active chlorine**	CYA	S/D/O/P
Input:					
Water surface (m)		AREAswimw	440	440	D
Average depth of water (m)		DEPTHswimw	1.8	1.8	D
Number of visitors per day (-)		Nvisit	400	400	D
Concentration in swimming water	(kg/m^3)	Cproc_chronic	0.005	0.1	S
Concentration of the active substance in swimming water after shock disinfection	(kg/m^3)	Cproc_acute	0.1	0.1	
Water replaced per visitor (m)		Vrepl	0.05	0.05	D
Output:					
Elocalwater_acute = Emission rate to waste water after shock disinfection [kg/d]					
Elocalwater_chronic = Emission rate to waster water, daily release [kg/d]					
Calculation:					
Elocalwater_acute = (AREAswim * DEPTHswim * Cproc) / 1 = 792 kg/d			79.2	79.2	kg/d
Elocalwater_chronic = (Nvisit * Vrepl * Cproc) / 1			0.1	2	kg/d

Table 4.2 Discharge of swimming water by public and private swimming pools into the surface water for the acute situation

Variable/parameter (unit)		Symbol	Active chlorine	CYA	S/D/O/P
Input:					
Type of swimming pool (public/private)		POOLTYPE			P
Dilution factor for (-):		DILUTION			D
public swimming pools			4	4	
private swimming pools			2	2	
Depth of ditch (m)		DEPTHditch °	0.3	0.3	D
Concentration in swimming water	(kg.m3)	Cproc	0.005	0.1	S
Parameters requiredfor distribution modules .					
Fraction drift related to location and way of application (-)		Fdrift	1	1	O[c]
c					
Application interval (d)		Tint	1	1	O[c]
Number of applications in one year (-)		Nappl	1	1	O'
Output:					
Public pools					
Cwaterpest-1appl = Cproc / dilution			0.00125	0.025	g/L
Private pools					
Cwaterpest-1appl = Cproc / dilution			0.0025	0.05	g/L

1) Already defined in distribution model for pesticides (symbol DEPTHditch)
2) use symbols with subscripts (Fdrift, Tinterval and Nappl respectively)

4. Water in casks, buckets, vases for flowers

Table 4.1 Discharge of treated water for flowers from flower auctions

Variable/parameter		Cyanuric acid	Unit
Product application dose	C	0.03	g/L
Step 1. amount of water used for cut flower treatment			
Number of cut flowers sold in Europe each year.	A	1.85E+10	stems per year in Europe

number of stems per liter	B	50	
Amount of water used in Europe per year		370200	m3 of water per year
Step 2. amount of product used for cut flowers treatment			
Formula: A/B x C =	D	11106	kg per year in Europe
Market share actisan	E	1	[-]
Actisan (D*E)	F	11106	kg per year in Europe
Step 3. amount of product emitted from NL auctions			
NL fraction of European market for cutflowers	G	0.88	[-]
Used in cut flowers industry in the Netherlands (F*G)	H	9773.28	kg per year in Netherlands
Flowers transported dry: water released by auctions	I	0.58	[-]
Amount released from auctions (G*H)	J	5668.50	kg per year in Netherlands from auctions
Number of auctions		6	Flora holland locations
Number of emission days		200	days
Amount emited per auction (J/days/8)		4.7	kg per day

5. Accommodations for animals and annexes

Emissions to soil and leaching to ground water after removal to manure storage after disinfection of animal accommodations.

Input values:

Table 5.1: Number of disinfection events and biocide application intervals; the subscript cat-subcat presents the animal (sub)category and for poultry the type of housing.

Cat-subcat	Category	Subcategory	Housing	Number of disinfection events in one year Napp-bioc [-]	Biocide application intervall Tbioc-int [d]	Reference
1	Cattle	Dairy cow		1	365	KTBL 2006 A)
2		Beef cattle		1	365	KTBL 2006
3		Veal calf		4	91	KTBL 2006
4/5	Pigs	Sows		5	73	KTBL 2006
6		Fattening pig		3	122	KTBL 2006
7	Poultry	Laying hen	Battery aeration	1	365	KTBL 2006
8			Deep pit, high-rise	1	365	KTBL 2006
9			Compact	1	365	KTBL 2006
10			Battery (no treatm.)	1	365	KTBL 2006
11			Free range, litter	1	365	KTBL 2006
12		Broiler	Free range, litter	7	52	KTBL 2006
13		Laying hen	Free range, grating	1	365	KTBL 2006
14		Parent broiler ≥18 weeks	Free range, grating	1	365	deduced from ESD for PT 18 No. 14, Table 5.6
15		Parent broiler in rearing = Parent broilers < 18 weeks	Free range, grating	3	122	KTBL 2006
16		Turkeys	Freer range, litter	2	182	KTBL 2006
17		Ducks	Free range, litter	13	28	KTBL 2006
18		Geese	Free range, litter	6	61	deduced from animal cvclus (= 9 weeks) (IMA 2009)

A) KTBL 2006 provides detailed data on animal husbandry (especially in the online version from which the information provided in the table is taken). For few animal categories or housing types only data on the number of stable cleaning events were available. In these cases, it is assumed that the number of cleaning events equals the number of disinfection events since disinfection of stables normally is carried out immediately after cleaning.

Table 5.1: Outcome of the scenario calculations ESD 18 treated manure to grassland and arable land for cyanuric acid

Scenario	RESULTS FOR SOIL (IN MG/KG)				RESULTS FOR GROUNDWATER (IN MG/L)			
	PIECsoil_grs_final		PIECsoil_arab_final		PIECgrs-grw-final		PIECars-grw-final	
	manure appl.	slurry appl.	manure appl.	slurry appl.	manure appl.	slurry appl.	manure appl.	slurry appl.
1	0.00E+00	1.74E-02	0.00E+00	1.95E-03	0.00E+00	1.43E-04	0.00E+00	1.61E-05
2	0.00E+00	9.86E-03	0.00E+00	1.11E-03	0.00E+00	8.12E-05	0.00E+00	9.11E-06
3	0.00E+00	2.76E-02	0.00E+00	1.48E-02	0.00E+00	2.27E-04	0.00E+00	1.22E-04
4	0.00E+00	1.55E-02	0.00E+00	1.13E-02	0.00E+00	1.28E-04	0.00E+00	9.27E-05
5	0.00E+00	1.97E-02	0.00E+00	1.43E-02	0.00E+00	1.62E-04	0.00E+00	1.18E-04
6	0.00E+00	1.28E-02	0.00E+00	5.55E-03	0.00E+00	1.05E-04	0.00E+00	4.57E-05
7	0.00E+00	4.63E-03	0.00E+00	6.27E-04	0.00E+00	3.81E-05	0.00E+00	5.16E-06
8	0.00E+00	5.09E-03	0.00E+00	7.00E-04	0.00E+00	4.19E-05	0.00E+00	5.76E-06
9	5.09E-03	0.00E+00	7.00E-04	0.00E+00	4.19E-05	0.00E+00	5.76E-06	0.00E+00
10	0.00E+00	5.09E-03	0.00E+00	7.00E-04	0.00E+00	4.19E-05	0.00E+00	5.76E-06
11	1.20E-02	0.00E+00	1.75E-03	0.00E+00	9.90E-05	0.00E+00	1.44E-05	0.00E+00
12	7.90E-03	0.00E+00	6.22E-03	0.00E+00	6.50E-05	0.00E+00	5.12E-05	0.00E+00
13	0.00E+00	8.96E-03	0.00E+00	1.30E-03	0.00E+00	7.37E-05	0.00E+00	1.07E-05
14	0.00E+00	4.82E-03	0.00E+00	6.83E-04	0.00E+00	3.97E-05	0.00E+00	5.62E-06
15	0.00E+00	1.16E-02	0.00E+00	4.36E-03	0.00E+00	9.51E-05	0.00E+00	3.59E-05
16	1.33E-02	0.00E+00	3.00E-03	0.00E+00	1.10E-04	0.00E+00	2.47E-05	0.00E+00
17	2.26E-02	0.00E+00	1.98E-02	0.00E+00	1.86E-04	0.00E+00	1.63E-04	0.00E+00
18	1.00E-02	0.00E+00	6.74E-03	0.00E+00	8.26E-05	0.00E+00	5.54E-05	0.00E+00

6 Vehicles for animal transport

6.a emission to soil at farms from disinfection of vehicles used for animal transport

Table 6.2: Emission scenario for the disinfection at farms of vehicles used for animal transport with direct release of chlorine to soil after treatment

Parameters	Nomenclature	Active chlorine	CYA	Unit
Inputs				
Area of 1 truck (mammal transports)	*AREAmam*	140	140	[m^2]
Content of active ingredient in formulation (dilution)	*Fbioc*	1.6	1.4	[$g.l^{-1}$]
Amount of (diluted) product prescribed to be used per m^2	$Vdil_{i2,i3}$	0.4	0.4	[$l.m^{-2}$]
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil} A)	1	1	[-]
Fraction released to air	$F_{air\ i2,i3,i4}$ B)	0.1	0.1	[-]
Fraction released to waste water	$Fsoil_{\ i2,i3,i4}$	($1-F_{air}$)	($1-F_{air}$)	[-]
Number of disinfectant applications in one year	*Napp-bioc*	365	365	[-]
Standard concentration in air at 100 m from source for a source strength of 1 $kg.d^{-1}$	$Cstd_{air}$ C)	2.78E-04	2.78E-04	[$mg.m^{-3}$]
Outputs				
Intermediate calculations				
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i2,i3}$			[kg]
Mammal transports: $Qai\text{-}prescr_{i2,i3} = 10^{-3} \cdot Fbioc \cdot Vprod_{i2,i3} \cdot F_{dil} \cdot AREAmam$		*0.0896*	*0.0784*	*kg/d*
Calculation				
Air exposure:				
$Edirect_{air\ i2,i3,i4} = Qai\text{-}air_{\ i2,i3,i4} = F_{air\ i2,i3,i4} \cdot Qai\text{-}prescr_{i2,i3}$		*0.00896*	*0.00784*	*kg/d*
$Cdirect_{air\ i2,i3,i4}$ =*Edirectair i2,i3,i4*•• *Cstdair*•*Napp-bioc /(365•10^6)*		2.49E-13	2.18E-13	mg/m3
Soil				
Qsoil i2,i3,i4 = Fsoil i2,i3,i4 • Qai-prescri2,i3,i4		*8.06E-02*	*7.06E-02*	kg/d

Soil surface area treated truck		*30*	*30*	m2
Volume		*3*	*3*	m3
RHO soil		*1700*	*1700*	kg/m3
Concentration in soil		*15.8*	*13.8*	mg/kg soil

b. Central disinfection:

Table 6.1: Emission scenario for the disinfection of vehicles used for animal transport Input for Cyanuric acid

Parameters	Nomenclature	CYA		Unit
Inputs				
Area of trucks (mammal transports)	*AREAmam*	4546	D	[m^2]
Area of trucks (poultry transports)	*AREApoul*	1120	D	[m^2]
Area of containers (poultry transports)	*AREAcont*	3355	D	[m^2]
Content of active ingredient in formulation (dilution)	*Fbioc*	1.4		[$g.l^{-1}$]
Amount of (diluted) product prescribed to be used per m^2	$Vdil_{i2,i3}$	0.4		[$l.m^{-2}$]
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil} A)	1		[-]
Fraction released to air	$F_{air\ i2,i3,i4}$ B)	0.1		[-]
Fraction released to waste water	$F_{stp\ i2,i3,i4}$	(1-F_{air})		[-]
Number of disinfectant applications in one year	*Napp-bioc*	365		[-]
Standard concentration in air at 100 m from source for a source strength of 1 kg.d^{-1}	$Cstd_{air}$ C)	2.78E-04		[$mg.m^{-3}$]
Outputs				
Air Exposure				
Emission to air from one application	$Qai\text{-}air_{i2,i3,i4}$ = $Edirect_{air\ i2,i3,i4}$			[kg]
Annual average concentration in air at 100 m from source	$Cdirect_{air\ i2,i3,i4}$			[$mg.m^{-3}$]
STP				
Emission from one application to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i2,i3,i4}$ = $Elocal_{waste\ water\ i2,i3,i4}$			[$kg.d^{-1}$]
Intermediate calculations				
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i2,i3}$			[kg]
Mammal transports: $Qai\text{-}prescr_{i2,i3} = 10^{-3} \cdot Fbioc \cdot Vprod_{i2,i3} \cdot F_{dil} \cdot AREAmam$		*2.90944*		*kg/d*
Poultry transports: $Qai\text{-}prescr_{i2,i3} = 10^{-3} \cdot Fbioc \cdot Vprod_{i2,i3} \cdot F_{dil} \cdot (AREApoul + AREAcont)$		*2.864*		*kg/d*
Calculation				
Air exposure:				
$Edirect_{air\ i2,i3,i4} = Qai\text{-}air_{i2,i3,i4} = F_{air\ i2,i3,i4} \cdot Qai\text{-}prescr_{i2,i3}$		*0.290944*		*kg/d*
$Cdirect_{air\ i2,i3,i4}$ =Edirectair i2,i3,i4·• Cstdair • Napp-bioc / (365 • 10^6)		*8.09E-12*		*mg/m3*
STP				
$Qai\text{-}stp_{i2,i3,i4} = F_{stp\ i2,i3,i4} \cdot Qai\text{-}prescr_{i2,i3,i4}$		*2.62*		*kg/d*

A) For example: If the formulation is diluted 1/10 (= 1:10), the dilution factor is 10^{-1}. If the formulation (product) is also used as working solution, the dilution factor is 1.

B) Default value for F_{air} derived from the A-tables of the TGD (IC = 1: AGRICULTURAL INDUSTRY; Table A3.1 – Default emission factor to air).

C) According to Technical Guidance Document on Risk Assessment (TGD) in support of … Directive 98/8/EC, Part II (EC 2003a).

7. Milking equipment on farms, including pipelines, tanks, machinery etc.

Table 7.1: Scenario description, parameters/variables and default for the disinfection of milking parlour systems (adopted from Baumann, 2000) emission of cyanuric acid

Parameters	Nomenclature	Value	Unit	Origin

Input				
Concentration of active ingredient	*Cform*	0.24	[g.l^{-1}]	S
Amount of disinfectant used for cleaning of the milking installation	$Vform_{inst}$	130 (= 2 • *65)*	[l.d^{-1}]	D
Amount of disinfectant used for cleaning of the milk storage tank	$Vform_{tank}$	45	[l.d^{-1}]	D
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	[-]	D
Fraction of the emission to waste water	F_{water}	1	[-]	D
Output				
Quantity of active ingredient used	*Qa.i.*	42	[g.d^{-1}]	O
Local emission to waste water	$Elocal_{3,water}$	0.042	[kg.d^{-1}]	O
Model calculation				
$Qa.i. = Cform_{.} \cdot (Vform_{inst} + Vform_{tank})$				
$Elocal_{water} = Qa.i. \cdot (1 - F_{dis}) \cdot F_{water} / 1000$				

8a. Locations where food and drinks are prepared or stored – surfaces, instruments, cleaning equipment

Table 8a: Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries (IHO 2006) calculated for cyanuric acid

Variable/parameter	Nomenclature	Slaughter houses	Kitchens / canteens	Unit	Total
Application rate of the product *plus dilution water*	Qappl	0.04	0.04	[l/m2]	
Concentration of active substance in the use solution	Cform	0.00072	0.00072	[kg/l]	
Surface of the treated area	S	10000	2000	[m2]	
Number of applications per day	Nappl	3	1	[d-1]	
Fraction of disinfectant emitted to the waste water	Fwater	1	1	[--]	
without pre-treatment		1	1		
with pre-treatment		0.1	0.1		
Fraction of substance disintegrated during or after application (before release to the sewer system)	[-]	0	0	F_{dis}	
Fraction of substance eliminated due to on-site pre-treatment of waste water	[-]	0	0	F_{elim}	
Output :					
Elocalwater = Local emission to waste water (without pre-treatment)					
Elocalwater_pre-treat = Local emission to waste water (with pre-treatment)					
Calculation:					**Sum**
Elocalwater = Qappl *Cprod * S * Nappl * Fwater * (1 - Fdis) • (1 – Felim)	[kg/d]	0.864	0.0576	[kg/d]	0.9216
Elocalwater_pre-treat = Qappl * Cprod * S * Nappl * Fwater * (1 - Fdis) • (1 – Felim)	[kg/d]	0.0864	0.00576	[kg/d]	0.09216

8b Beverage industry

Table 8b: Emission scenario for calculating the releases of disinfectants used in entire plants (e.g. breweries, dairies, beverage processing plants) (IHO 2006) Calculated for chlorine, sodiumdichlorocyanurate and cyanurate acid

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of biocidal active substance used per year in the local plant	*Qa.i.*	228*	[kg.yr^{-1}]	P (Table 6)
Number of emission days per year	*Temission*	231	[d.yr^{-1}]	D
Amount of biocidal active substance used per day in the local plant	*Qa.i.*	0.987	[kg.d^{-1}]	
Fraction released to wastewater	F_{water}	1	[-]	D

Fraction of substance eliminated due to on-site pre-treatment of the plant waste water	F_{elim}	0	[-]	D
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	[-]	D
Capacity of the STP			[$m^3.d^{-1}$]	D
On-site STP	$CAP_{STP\_on\text{-}site}$	52000000	L/a	
	$CAP_{STP\_on\text{-}site}$	113	m3/d	
Off-site STP (standard STP according to the TGD)	$CAP_{STP\_off\text{-}site}$	2000	[m3/d]	
Dilution factor in surface water (standard default according to the TGD) on-site	*DILon site*	10.0	[-]	S
Dilution factor in surface water (standard default according to the TGD) off-site	*Dil off site*	10		
Output				
Influent concentration of active substance in the STP	$C_{influent}$		[$mg.l^{-1}$]	O
Calculation				

On-site *treatment of waste water and direct release to surface water:*

$C_{influent}\ (PEC_{sw}) = (Qa.i. / Temission) \bullet 1{,}000 \bullet (1 - F_{dis}) \bullet (1 - F_{elim}) \bullet F_{water} / CAP_{STP\_on\text{-}site} * DIL$

Off-site *treatment of waste water:*

$C_{influent} = (Qa.i. / Temission) \bullet 1{,}000 \bullet (1 - F_{dis}) \bullet (1 - F_{elim}) \bullet F_{water} / CAP_{STP\_off\text{-}site}$

		Chlorine	*Sodium dichloroisocyanurate*	Cyanuric acid
PECstp on site	*mg/L*	*8.76E+00*	*1.38E+01*	8.07E+00
PECstp off site	*mg/L*	*4.94E-01*	*7.76E-01*	4.55E-01
PECsw on site	*mg/L*	*8.76E-01*	*1.38E+00*	8.07E-01
PECsw off site	*mg/L*	*4.94E-02*	*7.76E-02*	4.55E-02

* It is assumed that all chlorine in the plant is applied as sodiumdichloroisocyanurate tonnage