Toelatingsnummer 10620 N

Divosan TC 86

10620 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 VERLENGING TOELATING

Gelet op de aanvraag d.d. 18 september 2007 (20070983 TVB) van

Diversey B.V.
Maarssenbroeksedijk 2
3542 DN UTRECHT

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

Divosan TC 86

gelet op artikel 122, Wet gewasbeschermingsmiddelen en biociden,

BESLUIT HET COLLEGE als volgt:

1.1 Verlenging toelating

1. De toelating van het middel Divosan TC 86, welke expireert op 1 juni 2010 wordt voor de in bijlage I genoemde toepassingen verlengd onder nummer 10620. 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: vloeistof

werkzame stof:	*gehalte:*
natriumhypochloriet	45 g/l (als actief chloor)

letterlijk en zonder enige aanvulling:

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

gevaarsymbool:	*aanduiding:*
C	Bijtend
N	Milieugevaarlijk

Waarschuwingszinnen:

R35	-Veroorzaakt ernstige brandwonden.
R50	-Zeer vergiftig voor in het water levende organismen.

Veiligheidsaanbevelingen:

S21	-Niet roken tijdens gebruik.
S26/28-NL	-Bij aanraking met de ogen of de huid onmiddellijk met overvloedig water afspoelen en deskundig medisch advies inwinnen.
S36/37/39b	-Draag geschikte beschermende kleding, handschoenen en een beschermingsmiddel voor het gezicht.
S45	-Bij een ongeval of indien men zich onwel voelt onmiddellijk een arts raadplegen (indien mogelijk hem dit etiket tonen).
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:

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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 Divosan TC 86 is laatstelijk bij besluit d.d. 21 december 2001 verlengd tot 1 juni 2010. Het betreft een aanvraag tot verlenging van de toelating van het middel Divosan TC 86 (10620 N), een middel op basis van de werkzame stof(fen) natriumhypochloriet. De verlenging wordt aangevraagd voor de toelating als desinfectiemiddel op plaatsen waar eet – en drinkwaren worden bereid, behandeld of bewaard, echter met uitzondering van keukens van instellingen voor gezondheidszorg.

2.2 Informatie met betrekking tot de stof
De werkzame stof natriumhypochloriet is genotificeerd voor o.a. productsoorten 2 en 4. Er is nog geen besluit genomen tot plaatsing op bijlage 1, 1A of 1B van de biociderichtlijn 98/8/EG.

2.3 Karakterisering van het middel
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2.4 Voorgeschiedenis
De aanvraag is op 18 september 2007 ontvangen; op 19 september 2007 zijn de verschuldigde aanvraagkosten ontvangen. Bij brief d.d. 1 januari 2010 is de aanvraag in behandeling genomen.

2.5 Eindconclusie
Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel Divosan TC 86 op basis van de werkzame stof natriumhypochloriet 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, 28 mei 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. 28 mei 2010 tot verlenging van de toelating van het middel Divosan TC 86, toelatingnummer 10620 N

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als desinfectiemiddel op plaatsen waar eet – en drinkwaren worden bereid, behandeld of bewaard, echter met uitzondering van keukens van instellingen voor gezondheidszorg.

B.
GEBRUIKSAANWIJZING

Het middel is werkzaam tegen een aantal bacteriën en gisten.

- Sterk verontreinigde oppervlakken en materialen vooraf grondig reinigen met een geschikt reinigingsmiddel en vervolgens afspoelen met schoon water. Overtollige vloeistof verwijderen. Licht verontreinigde oppervlakken en materialen kunnen met dit gecombineerde reinigings – en desinfectiemiddel in een gang worden behandeld.

- Indien behandelde oppervlakken of materialen met eet – en drinkwaren in contact kunnen komen, is na de inwerkingstijd grondig naspoelen met schoon water vereist.

- Minimale inwerkingstijd 5 minuten.

Op plaatsen waar eet – en drinkwaren worden bereid, behandeld of bewaard, is de gebruiksconcentratie 0,50 – 0,75%.

Voor circulatiesystemen gelden de volgende richtlijnen:

Zuivel, frisdrank –en voedingsmiddelenindustrie

Voorspoelen met schoon, lauw water
10 minuten circuleren met een 0,75% -ige oplossing.
Naspoelen met schoon, koud water.

Bierbrouwerijen
Voorspoelen met schoon, koud water.
10 – 30 minuten circuleren met een 1 – 3% -ige oplossing.
Naspoelen met schoon, koud water.

Voor melkwinningsapparatuur op de boerderij geldt de volgende richtlijn:

Voorspoelen met schoon, lauw water.
Reinigen en desinfecteren met een 0,5% -ige oplossing gedurende 10 minuten.
De aanvangstemperatuur dient tenminste 60 –70 °C te bedragen.Naspoelen met schoon, koud water.

Attentie
Eenmaal per week circuleren met een zuur oplossing van 50 – 60°C.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 28 mei 2010 tot verlenging van de toelating van het middel Divosan TC 86, toelatingnummer 10620 N

RISKMANAGEMENT

Contents **Page**

H.1 Introduction

This assessments concerns prolongations of authorisations of Biocidal products based on the active substance sodium hypochlorite. Biocidal function of the sodium hypochlorite containing products is mainly based on the active chlorine component within the suspension.

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

Table H.1 Overview of intended use

Use scenario	Product	Name a.s.	A.s. concen-tration in product	Dosage product
		PT2		
Cleanroom departments in industrial, institutional and laboratorial settings (hospitals, other public health areas and veterinary sector excluded)	Premier Klercide-Cr Sterile Biocide E	Active chlorine	0.71%	40 ml/m^2
		PT4		
Disinfection of milking equipment (pipelines, tanks, machinery, etc.) on farms	1. Calgonit Da Super 2. Divosan Tc 86 3. Fink-Vetoplosmiddel 4. Hyproclor Plus 5. Reiclor	Active chlorine	1. 3.68% 2. 4.5% 3. 4.75% 4. 6.4% 5. 4.0%	1. 5 ml/L 2. 5 ml/L 3. 5 ml/L 4. 5 ml/L 5. 5 ml/L
Disinfection of areas for preparation, treatment or storage of food and drinks	1. Cleaner Ps-Nf Super 2. Divosan Tc 86 3. Fink Fc 21 4. Fink-Vetoplosmiddel	Active chlorine	1. 3.5% 2. 4.5% 3. 4.75% 4. 6.4%	1. 5 ml/L 2. 5-7.5 ml/L 3. 10 ml/L 4. 20 ml/L
Disinfection of milking equipment in dairy and/or breweries and/or soft drinks and/or food industries	1. Calgonit Da Super 2. Divosan Tc 86	Active chlorine	1. 3.68% 2. 4.5%	1. 5 ml/L 2. 7.5 ml/L

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

Intended Uses

In order to facilitate the work in granting or reviewing authorisations, the intended uses of the substance are summarized as:

Product Type PT04 (Food and feed area disinfectants).
The biocidal products Fink - FC 21, Fink Vetoplosmiddel, Cleaner PS-NF Super, Divosan TC 86, Reiclor, Hyproclor Plus and Calgonit DA Super control and inhibits the growth of bacteria (spores excluded) and yeasts for application aim 1) desinfection of milking equipement (pipelines, tanks, machinery etc.) on farms (Reiclor, Hyproclor Plus, Fink Vetoplosmiddel, Calogonit DA Super, Divosan TC 86), 2) desinfection of surfaces in areas for preparation, treatment or storage of food and drinks (Fink FC 21, Fink Vetoplosmiddel, Divosan TC 86, Cleaner PS-NF Super) and 3) disinfection in only diary industry (Calgonit DA Super) and diary industry, beverage and food industry as well as beer breweries (Divosan TC 86).
The concentration a.s in the product varies between 3.68% and 6.4% (w/w) active chlorine for application aim 1, between 3.7 and 4.75% (w/w) active chlorine for application 2 and between 3.68% and 4.5% (w/w) active chlorine for application aim 3.
The dosage used varies between 0.5% for application aim 1 (0.33 g active chlorine/L), max. 2% for application aim 2 (Fink Vetoplosmiddel; 1.2 g active chlorine/L) and max. 3% for application aim 3 (Divosan TC 86; 1.7 g active chlorine/L).
The clean in place system will be used for application aim 1 and 3. Sponge, brush or cloth or other non-specified equipement will be used for application aim 2.

Product Type PT02.01 (Private area and public health area disinfectants)

The product Premier Klercide –CR sterile Biocide E was claimed for control of bacteria, yeast and fungi for disinfection of cleanroom departments in industrial, institutional and laboratorial seetings (hospitals other public health areas and veterinary sector excluded).
The concentration in the product is 0.71% active chlorine. The dosage used will be 40 ml/m2 (0.28 g active chlorine/m2).
A mopping and wiping system will be used.

In principle, a “worst case tiered approach” will be considered in the evaluation performed for the different aspects. Using the worst case approach the risk assessment used for the prolongation of different formulations with also different applications based on the same substance will be based on the application to be expected to cause the highest risk. Additional tiers could be necessary in cases there are adverse effects expected for humans and/or environment leading to non-authorisation for the worst case application.
The “worst case tiered approach” will be considered for the aspects separately.

Human health effects assessment active substance
Sodium hypochlorite is an existing active substance, not included in Annex I of 98/8/EG. An application for inclusion is submitted, for which Italy is the Reporting Member State. A draft concept CA-report does not exist for sodium hypochlorite, therefore this assessment is based on the physical chemical and toxicological data as published by the European Chemicals Bureau in a IUCLID dataset and the information provided in the draft Risk Assessment Report on sodium hypochlorite (May 2005). These data are summarised by TNO, rapport CTB-2005-016-TOX-NL, October 2005.

Toxicological profile of sodium hypochlorite

Toxicokinetics

In rats, after oral doses of 0.6 or 0.75 labelled hypochlorite mg/animal (ca. 2.4 or 3.0 mg/kg bw, calculated assuming a body weight of 0.25 kg), plasma levels peaked after 4 hours. Elimination half-life was 88.5 hours. Distribution was highest in plasma, and 96 hours after intake 36.4% of the administered dose had been excreted in urine and 14.8% in faeces. Oral absorption was at least 36.4%, based on urinary excretion only, as the RAR-summary did not quantify the amount recovered from tissues, organs and residual carcass.

In rats exposed to 7 mL of an 8 mg/L solution of sodium hypochlorite at pH 7.9, acetic acid was found in blood and stomach content. *In vitro* and *in vivo* tests (not further specified) with rat stomach fluid revealed the formation of chloramines.

Toxicodynamics

Acute toxicity

In the RAR an oral LD_{50} of a 12.5% sodium hypochlorite solution in rats of > 5.8 mg/kg bw is reported. Because the acute toxicity of corrosive substances is more related to concentration than to dose, extrapolation from data obtained from using a hypochlorite solution to a fictive 100% sodium hypochlorite is not relevant. As the highest concentrations of hypochlorite solutions as industrially produced and marketed are about 15%, and solutions marketed for consumer use are typically 5% or less, it can be concluded from the data presented in the RAR that hypochlorite solutions are of low acute oral toxicity.

One acute inhalation LC_{50} for rats was reported: it was >10 mg/L. According to the RAR, the original report did not indicate which concentration of sodium hypochlorite was used.

One acute dermal toxicity study with rabbits was described, again without indicating which concentration of sodium hypochlorite was used. The dermal LD_{50} for rabbits was reported to be >10 g/kg bw. Quite a number of skin and eye irritation tests were executed with various sodium hypochlorite solutions, mainly with rabbits. Depending on the concentration, sodium hypochlorite solutions were proven to be irritating to skin and eyes or even corrosive. In accordance to Table 3.2 of Regulation (EC) 1272/2008 solutions above 10% are classified as corrosive (R34) and solutions with concentrations between 5 and 10% as irritating to eyes and skin (R36/38).

Several case reports for sensitivity were described in which human patients tested positive in a patch test with sodium hypochlorite. However, they all date from before chromium salts were taken out of the commercial products. These chromium salts were held responsible for the occasional skin sensitisation due to the use of hypochlorite solutions. Furthermore, these studies were poorly reported and not fully conclusive. One study was reported in which 3 out of 225 patients, tested with 0.5% sodium hypochlorite, showed a positive reaction in the patch test. Two sensitisation tests in Guinea pigs (20 animals tested) and two in humans (86 and 90 tested, respectively) did not produce any positive individuals. Based on this information, no classification of sodium hypochlorite for skin sensitisation would be required as reported animal tests are negative and not a substantial number of persons was proven to be inducible in patch tests with sodium hypochlorite.

Short-term and chronic toxicity

No standard 28-day or 90-day repeated dose toxicity studies on sodium hypochlorite in animals by the oral route have been reported. However, the data available from non-standard studies are sufficient to derive a NOAEL for sodium hypochlorite by this route of exposure. The dermal toxicity studies reflect the reversible irritant effects of sodium hypochlorite at the doses tested.
A general decrease of body weight or body weight gain was usually observed following treatment with the highest doses used, most probably due to a secondary effect linked to low water consumption.

In male and female rats treated with 0.2% and 0.4% of sodium hypochlorite in drinking water for 90 days, a decrease in body weight and in specific organ weights, associated with some biochemical changes, were reported. A NOEL of 0.1% of sodium hypochlorite (950 mg/l available chlorine or 49.9

mg/kg bw/d[1]) can be derived from this study.

Rats were given sodium hypochlorite dissolved in their drinking water at concentrations of 0, 0.05, 0.1, 0.2 or 0.4 % for 92 days (corresponding 0, 475, 950, 1900, 3800 mg/l available chlorine). At the highest dose group both male and female rats showed a significant decrease in body weight gain (47% and 31% reduction in males and females respectively compared to controls) as well as significant reductions in the absolute weights of certain organs. However, the organ weight to body weight ratios were not reported and so the true significance of these findings could not be established. The NOEL for sodium hypochlorite in the study was 0.2 % for both males and females (46.6 and 102 mg/kg/d, respectively considering the drinking water intakes reported in the study).

Some slight effects on body weight or specific organ weights were shown in male mice treated with 275 mg/l available chlorine in drinking water for two years. The NOEL in this study was 140 ppm available chlorine or 23.3 mg/kg bw/d.

Some incidental effects related to the immune system were reported in rats and mice administered with low doses of sodium hypochlorite in chlorinated water for 12 or 17 weeks. These effects were observed in rats receiving chlorinated water containing 15-30 mg/l available chlorine (about 0.75-1.5 mg/kg bw/day). However, in long term studies, no differences were reported between treated and controls for haematological analysis or thymus weight in rats given higher doses of sodium hypochlorite in water (275 mg/l available chlorine or 13.75 mg/kg bw/d) (National Toxicology Program (NTP), 1992). It is not possible to derive a no effect level for this specific end-point.

No effects were observed in the dermal studies except for specific skin toxicity in Guinea pigs (marginally lowered *in vitro* basal cell viability) of uncertain toxicological relevance at 0.5% sodium hypochlorite solution, which is related to the acute irritant effects of the substance. In the same test, no effects were observed with a 0.1% sodium hypochlorite solution. In a skin two-stage carcinogenesis model study a clear no effect level was observed in female mice treated for 51 weeks with 1% sodium hypochlorite solution. Analysis of the number of skin tumours, squamous cell carcinoma and epidermal hyperplasia was performed. No animals died and no epidermal hyperplasia was observed in the treated group.

No repeated dose inhalation toxicity studies are available on sodium hypochlorite aerosol, either in animals or humans.

Carcinogenicity
The potential carcinogenicity of sodium hypochlorite has been examined in rats and mice by long-term oral administration in drinking water. Its potential carcinogenicity has also been studied in a multigeneration study by the oral administration of chlorinated drinking water to rats. There are no reports of carcinogenicity studies by the dermal or inhalation route, except for a number of dermal studies on the possible role of sodium hypochlorite as a co-carcinogen or tumour promoter. No other evidence is reported in other tests.

In long-term carcinogenicity studies, sodium hypochlorite administered in the drinking water did not increase the proportion of rats and mice with tumours. Under the conditions of the 2-year NTP drinking water study there was no evidence of carcinogenic activity of chlorinated water in male rats or in male and female mice. However, the study concluded that there was equivocal evidence of carcinogenic activity of chlorinated water in female rats based on a marginal statistical increase in the incidence of mononuclear cell leukaemia. Similarly non-dose dependant increases in lymphoma/leukaemia were found in female Sprague-Dawley rats in another long-term rodent bio-assay with chlorinated drinking water. This study was deemed suggestive but inconclusive by its authors. Drinking water containing 100 mg/l chlorine was tested for carcinogenicity in a multigeneration study in male and female BDII rats. No increase in the incidence of tumours was seen in the treated animals relative to controls through six generations. Taking into account all the available information, it is concluded that carcinogenicity is not a relevant endpoint after oral exposure.

In dermal tumour promotion studies sodium hypochlorite applied to the skin did not produce skin tumours in mice. However, some effect was seen in the study with 4-nitroquinoline-1-oxide, while no skin promoting effect was observed with DMBA. These data suggests that sodium hypochlorite might have tumour-promoting effects, although it raises methodological questions and its quality cannot be

fully evaluated because of the lack of details.

No human data are available on carcinogenicity and the only data are related to chlorinated drinking water for which the epidemiological data are not sufficient to suggest a causal relationship between the use of chlorinated drinking water and increased cancer risk.

The International Agency for Research on Cancer has concluded that there is inadequate evidence for the carcinogenicity of sodium hypochlorite in animals and that sodium hypochlorite is not classifiable as to its carcinogenicity in humans (Group 3). This conclusion is still valid, taken into account the more recent available data.

A summary of the studies reported in the IUCLID dataset and in the RAR is presented in Table T. 1.

Table T. 1 Relevant NOAEL's/LOAEL's, most important toxic effects of sodium hypochlorite

study, route, species (sex)	doses[a]	NOAEL (mg/kg bw/d)[b]	LOAEL	Effects	Validity
Subacute, semi-chronic					
9 d, oral, rat (m)	40, 200, 1000 mg/L milk	>210	--	no adverse effects observed	3
14 d, oral, rat (f)	8, 40, 200 mg available chlorine/kg bw	42	210	increased kidney weights	3
14-28 d, oral, mouse (no data)	25-30 ppm (ca. 5 mg/kg bw/d)	--	ca. 5 mg/kg	impairment of macrophage function	3
35 d, oral, guinea pig	50 mg available chlorine/L	>50 mg available chlorine/L	--	no adverse effects observed	3
42 d, oral, rat (m)	20, 40, 80 mg/L	>16.5	--	no adverse effects observed	3
63 d, oral, rat (m)	5, 15, 30 mg active chlorine/L	0.25	0.75	increased prostaglandin E2, reduced macrophage oxidative metabolism	3
90 d, oral, rat (m, f)	120, 240, 480, 950, 1900 and 3800 mg/L available chlorine	49.9	ca. 100	decrease in body weight and in specific organ weights, associated with some biochemical changes	2
92 d, oral, rat (m, f)	0.025, 0.05, 0.1, 0.2, 0.4% in water	46.6	102	decreased body weight gain	2
Chronic, carcinogenicity					
12 m, oral, rat (m)	1, 10, 100 active chlorine mg/L	1.1 mg/L	11 mg/L	decrease of blood glutathione, increase of osmotic fragility, but not dose-related	3
24 m, oral, rat (m,f)	70, 140, 275 ppm active chlorine	>15	--	no treatment-related adverse effects	2
		--	--	equivocal evidence of carcinogenicity in females: marginal increase in leukaemia (not dose-related)	1
24 m, oral, rat (m,f)	475 and 950 active chlorine mg/L (m); 950 and 1900 active chlorine mg/L (f)	499 mg/L (m) 998 mg/L (f)	998 mg/L (m) 1995 mg/L (f)	reduced body weight, some single effects on organ weights	2
		>998 mg/L (m) >1995 mg/L	--	no increased tumour incidences	1

		(f)			
whole life, oral, rat (m,f)	100 mg free chlorine/L	>100 mg free chlorine/L	--	no increased tumour incidences no toxic effects on growth, blood picture and histology of liver, spleen, kidneys and other organs	3
24 m, oral, rat (m,f)	100, 500, 750 active chlorine mg/L	--	100 mg/L	not dose-related increase in lymphomas-leukaemias (no other end-points reported in RAR)	1
24 m, oral, mouse (m,f)	70, 140, 275 ppm active chlorine	23 >46	46 --	reduced body weight no evidence of carcinogenicity in males and females	2 1
24 m, oral, mouse (m,f)	475 and 950 active chlorine mg/L	>998 mg/L	--	no evidence of carcinogenicity in males and females	1

[a] expressed as NaOCl unless otherwise indicated in the table

[b] Calculated from available mg Cl_2/kg bw/d data presented by the RAR by multiplication with MW (NaOCl)/MW(Cl_2) = 74.4/71 = 1.05. If available mg Cl_2/kg bw/d data not provided by RAR, the original units were used as indicated in the table. For active chlorine is the same calculation method is used.

Genotoxicity
Sodium hypochlorite has been studied in a fairly extensive range of mutagenicity assays, both *in vitro* and *in vivo*. There are deficiencies in the conduct and/or reporting of most of the studies. The positive results produced in bacteria assays and the induction of chromosome aberrations (including gaps) and SCE in mammalian cells suggest, even if mammalian cell gene mutation studies are lacking, that sodium hypochlorite may exert an *in vitro* mutagenic activity. Sodium hypochlorite was without effect in a well-conducted mouse micronucleus assay suggesting that sodium hypochlorite is not clastogenic *in vivo*.

Reproduction en developmental toxicity
There are no relevant studies of sodium hypochlorite *per se* looking at its reproductive toxicity potential in animals. However, relevant studies have been conducted using chlorine as the test substance, administered in solution by gavage or in drinking water.

In a teratogenicity study, in which exposure was confined to the gestation period, no significant differences in the incidence of skeletal or soft tissue abnormalities were observed in treated groups when compared to controls. A small, but statistically significant increase in sperm head abnormalities was seen in mice, although the effect was not dose-dependent. However, no effects were seen in a well-conducted one-generation reproductive toxicity study in rats up to a concentration of 5 mg/kg bw of aqueous chlorine (expressed as sodium hypochlorite, maximum dose tested). Even if the value is expressed as sodium hypochlorite, it is equivalent to available chlorine since the measure method used detects all the chlorine species in water. Long-term toxicity studies provide also additional assurance that the substance is not a reproductive toxicant, as they did not identify the testes or ovaries as target organs.
There are no studies performed at dose levels able to induce systemic toxicity.

Neurotoxicity
No specific neurotoxicity testing was reported in the IUCLID dataset nor in the RAR. In the summaries of all other studies described in these documents no neurotoxic effects were reported.

Dermal Absorption
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.

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

PT04: The biocidal products Fink - FC 21, Fink Vetoplosmiddel, Cleaner PS-NF Super, Divosan TC 86, Reiclor, Hyproclor Plus and Calgonit DA Super control and inhibits the growth of bacteria (spores excluded) and yeasts for application aim 1) desinfection of milking equipement (pipelines, tanks, machinery etc.) on farms (Reiclor, Hyproclor Plus, Fink Vetoplosmiddel, Calogonit DA Super, Divosan TC 86), 2) desinfection of surfaces in areas for preparation, treatment or storage of food and drinks (Fink FC 21, Fink Vetoplosmiddel, Divosan TC 86, Cleaner PS-NF Super) and 3) disinfection in only diary industry (Calgonit DA Super) and diary industry, beverage and food industry as well as beer breweries (Divosan TC 86).

PT02.01: The product Premier Klercide –CR sterile Biocide E was claimed for control of bacteria, yeast and fungi for disinfection of cleanroom departments in industrial, institutional and laboratorial seetings (hospitals other public health areas and veterinary sector excluded).

6.1.2 Professional exposure

The professional user can be exposed to the products during the following applications:

- Mixing/loading of the clean in place system (automatic use) or mixing/loading to prepare the solution to clean equipement (manual use) (6.4 % sodium hypochlorite for Hyproclor Plus at maximum corresponding to 80 g active chloor /L at maximum*)
- Dipping, sponge, brush or cloth or mopping and wiping (0.03 % sodium hypochlorite for Hyproclor Plus at maximum (6.4x0.5%) corresponding to 0.4 g active chloor /L at maximum (6.4x12.5x0.5%*))
- Possibly spraying with a coarse spray for Divosan TC 86 (not excluded based on WG/GAs and taken into account as worst case for inhalatory exposure) (0.03 % sodium hypochlorite at maximum (4.5X0.75) corresponding to 0.42 g active chloor /L at maximum (4.5x12.5x0.75%*))

*1% w/w sodium hypochlorite solution = 12.5 g/l active chlorine

6.1.3 Non-professional exposure

The product is only used by professional users.

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

The products (PT04) are used as a disinfectant in places where food and drinks are prepared treated or stored. Therefore exposure to the general public is possible via migration of residues into food.

6.2 Human health effects assessment product

6.2.1 Toxicity of the formulated product

The toxicity of the formulated products do 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

Due to its corrosive properties, sodium hypochlorite produces local effects after a single exposure (skin and eye irritation) and repeated exposure (GI-tract irritation for oral toxicity studies and skin irritation in dermal toxicity studies). 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 (AECoral) 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 AECdermal 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. Applying an overall assessment factor of 10 for inter- and intraspecies variability a local inhalation limit concentration (AECinhalation) of 0.1 mg/m3 is derived.

For all applications should be noted that concentrations of 5% sodium hypochlorite are world-wide free available. Household bleach is freely available for domestic uses containing 5% sodium hypochlorite.

6.3.2 Professional users

The 3 different applications of the products and diluted product present the scenarios to be taken into account in the risk assessment (see 6.1.2). Because the risk assessment will be based on local effects mixing and loading with 6.4% sodium hypochlorite for Hyproclor Plus (highest concentrations used) will be the worst case exposure scenario for dermal exposure. For inhalatory exposure coarse spraying with 0.03% sodium hypochlorite for Divosan TC 86 will be the worst case exposure scenario. Other applications with possible consequences for labelling are described separately.

Worst case exposure scenario for dermal exposure
During mixing and loading, the professional user is dermally exposed to 6.4% (w/w) active chlorine at maximum, exceeding the AECdermal.Therefore, during mixing and loading a face mask, gloves and coverall is required for all products. Sodium hypochlorite is not volatile, so the inhalatory exposure during mixing and loading is considered to be negligible.

Worst case exposure scenario for inhalatory exposure
Application via spraying as supposed for Divosan TC 86 will be restricted to coarse spray leading to local effects. Therefore no inhalatory exposure is expected during application. However, the upper respiratory tract can be exposed to the diluted product with 0.03% sodium hypochlorite (0.42 g active chlorine /L). As labeling with R37 'Irritating to respiratory system' is mandatory for solutions containing more than 35%-<50%, it is concluded that no protective respiratory equipment for using the diluted product is necessary.

Other applications
By using all products mentioned the professional can be exposed during dipping, application with sponge, brush or cloth or mopping and wiping. The concentration sodium hypochlorite in the diluted product is 0,71% active chlorine /L at maximum. This concentration is lower than the 5% sodium hypochlorite solutions (62.5 g active chloor /L as household bleach freely available for domestic uses. As labelling with risk sentences to prevent dermal exposure and adverse effects is not mandatory for the diluted solutions protective dermal equipment as suitable gloves and protective clothing together with eye/face protection for using the product seems not necessary. However, as a professional user is more frequently dermally exposed and during application the professional user could be dermally exposed to 0.71% (w/w) active chlorine at maximum and 0.02% at minimum, exceeding the AECdermal, a face mask, gloves and coverall are required for all products during application.

On the basis of the above considerations, it can be concluded that the risk for the professional user is acceptable. The applications are not specified enough therefore only coarse spraying and not high pressure spraying or fogging is taken into account in the risk assessment.

6.3.3 Non-professional users, including the general public

The products are prescribed to be used by professional users.

6.3.4 Indirect exposure as a result of use

Products based on sodium hypochlorite are used for the disinfection of equipement/surfaces possible coming into contact with food (PT04). Therefore, secondary exposure of humans to sodium hypochlorite residues could occur by eating food. For the disinfection is indicated in the WG/GA that after treatment instruments and also surfaces should be rinsed thoroughly with tap water. The rinsing step will prevent direct exposure of food thereby preventing indirect exposure to sodium hypochlorite residues.

When used according to the WG/GA (which has to include "If treated surfaces or materials can come into contact with food and/or drinks, then thoroughly rinse with tap water after treatment", it can be concluded that no adverse health effects are expected for the general public, to sodium hypochlorite as a result of the application of all products.

6.3.5 *Combined exposure*

The products contain only one active substance and it is not described that it should be used in combination with other formulations.

6.4 Overall conclusions

Based on the risk assessment, no adverse health effects are expected for the protected professional user after dermal and respiratory exposure and for the general public to sodium hypochlorite as a result of the application of the products based on the active substance sodium hypochlorite. Personal protective equipment (gloves, suitable protective clothing and eye/face protection) is prescribed considering the skin and eye irritation properties of the active substance for all products for mixing and loading and application.

No further information is required.

6.5 Classification and labelling of the formulation concerning health

The current classification and labelling, which are prepared in conformity with Directive 1999/45/EC, can be maintained.

H.7 Environment

Introduction

The risk assessment for proposed application with active substance sodium hypochlorite is done in accordance with Chapter 10 of the RGB [Transition period for guidelines 91/414/EC and 98/08/EC] for products based on active substances which have not been placed on Annex I of Directive 98/8/EC.

It concerns a prolongation for authorisation of the biocidal products Fink - FC 21, Fink Vetoplosmiddel, Cleaner PS-NF Super, Divosan TC 86, Premier Klercide-CR Sterile Biocide E, Reiclor, Hyproclor Plus and Calgonit DA Super containing the active substance sodium hypochlorite. The biocidal products concern disinfectants for application in product types PT2 (Private area and public health area disinfectants) and PT4 (Food and feed area disinfectants).
Sodium hypochlorite, the active substance in the product, is notified for PT2 and PT4. Sodium hypochlorite is not included on Annex I of directive 98/8/EC and no list of endpoints is available. The CA report for Sodium hypochlorite PT02, PT04 (CAS 7681-52-9) was expected by18/02/2009, but is not publicly available yet. RMS is Italy.

The intended use is described in table E.1.

Table E.1. Intended uses

No.	Field of use envisaged	A.s. concentration in product	Dosage product
	Cleanroom departments in industrial, institutional and laboratorial settings (hospitals, other public health areas and veterinary sector excluded). [PT2]		
1	PREMIER KLERCIDE – E	0.71% active chlorine	40 ml/m²
	Disinfection of milking equipment (pipelines, tanks, machinery, etc.) on farms. [PT4]		
2	Reiclor	4.0% (w/w) active chlorine	5 ml/L
3	Hyproclor Plus	6,4% (w/w) active chlorine	5 ml/L
4a	Fink Vetoplosmiddel	4,75% active chlorine	5 ml/L
5a	Calgonit DA Super	3.68% (w/w) active chlorine	5 ml/L
6a	Divosan TC 86	4,5% active chlorine	5 ml/L
	Disinfection of areas for preparation, treatment or storage of food and drinks.[PT4]		
4b	Fink Vetoplosmiddel	4,75% active chlorine	20 ml/L
7	Fink FC 21	4.75% active chlorine	10 ml/L
6b	Divosan TC 86	4,5% active chlorine	5 -7.5 ml/L
8	Cleaner PS-NF Super	35 g/l active chlorine	5 ml/L
	Disinfection of milking equipment in dairy and/or breweries and/or soft drinks and/or food industries. [PT4]		
5b	Calgonit DA Super	3.68% (w/w) active chlorine	5 ml/L
6c	Divosan TC 86	4,5% active chlorine	7.5 - 30 ml/L

Environmental profile of active substance

The environmental profile of sodium hypochorite is presented in Appendix I. The data do not originate from the List of Endpoints of a CA report, but derive from earlier risk assessments performed by Ctgb for the a.s., and are available in C204.3.1 (6/4/09) and C197.3.1 (5/9/08).

7.1 Product related studies

Product related studies

The exposure assessment is based on data for the active substance. No specific product data are available on fate or ecotoxicity.

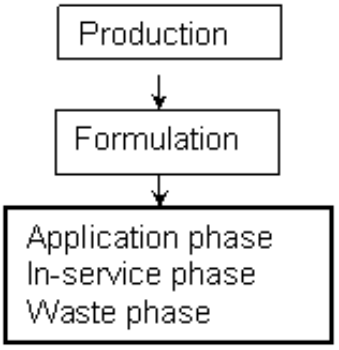
7.2 Environmental exposure assessment product

7.2.1 Chemistry and/or metabolism

The risk assessment is carried out for the active substance. Considering the fast decomposition of the product no metabolites are expected at a level higher than 10% of the active substance..

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. Compared to emissions from the application phase, service life and waste phase of the product, emissions from a.s. production and product formulation are considered less relevant. In the text below, general information is presented on the application of biocides for proposed uses

PT2 (Private area and public health area disinfectants)
Proposed uses for PT2 products concern application in clean room departments in industrial, institutional and laboratorial settings (hospitals, other public health areas and veterinary sector generally are excluded).
For PT2 products, applied indoors, releases to the environment occur in the waste phase, when residues of the product are removed to the sewer system. Emission to the STP is considered as the major emission route. 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.. Emission to air may occur during and after application of the product due to ventilation Emission to soil is considered negligible.

PT4 (Food and feed area disinfectants)
Proposed uses for PT4 products concern two categories 1) disinfection of milking equipment (pipelines, tanks, machinery etc.) on farms and 2) disinfection of equipment and areas for preparation, treatment or storage in general and in dairy, breweries, soft drinks and food industries.
When milking equipment disinfectants are applied on farms, active substance releases end up in the sewer or manure pit. When disinfectants are applied in industries, houses or institutions, active substance releases end up in a sewage treatment plant. 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.. Emission to air may occur during and after application of the product due to ventilation. Emission to soil is considered negligible.

The foreseeable routes of entry into the environment 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

		Environmental compartments and groups of organisms exposed					
No	**Use scenario**	**STP**	**Freshwater***	**Saltwater***	**Soil****	**Air**	**Birds and mammals**
1	Surface disinfection in clean room departments	++	+	-	-	(+)	(+)
2	Disinfection of milking equipment and materials (pipelines, tanks, machinery etc.) on farms	++	+	-	-	(+)	(+)
3	Disinfection of equipment and areas for preparation, treatment or storage of food and drinks in industry and institutions.	++	+	-	-	(+)	(+)

++ Compartment directly exposed
+ Compartment indirectly exposed (surface water from STP discharge, vertebrates eating

contaminated fish)
(+) Compartment potentially exposed (but unlikely significant concern due to a.s. hazard data and scale of exposure)
- 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

7.3 Risk characterisation for the environment

7.3.1 Aquatic compartment (incl. Sediment) and STP

Water and sediment organisms
The proposed application of the product excludes direct emission to surface water when used according to the proposed label.
The risk of the use of hypochlorite to water and sediment organisms during discharge of wastewater through a STP is expected to be negligible as hypochlorite, hypochloric acid or free chlorine is not present in the wastewater anymore after passage of the STP.
Therefore, the standards for water and sediment organisms are met.

STP
Hypochlorite is a very reactive compound. During and after the use of hypochlorite the concentration strongly decreases when hypochlorite reacts through a chain of reactions and disappears while forming chlorine. Residues will react with organic matter present in the pipeline system that discharges to the STP. The wastewater discharged to the sewer system will normally contain no hypochlorite, hypochloric acid or free chlorine because of the degradation processes that occur in the sewer system.
No unacceptable risks for micro-organisms in the STP are expected.
Therefore, the standard for micro-organisms in the STP is met.

Surface water intended for the abstraction of drinking water
It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion 'surface water intended for drinking water production'. No mathematical model for this aspect is available. This means that any data that is available cannot be adequately taken into account. It is therefore not possible to arrive at a scientifically well-founded assessment according to this criterion. The Ctgb has not been given the instruments for testing surface water from which drinking water is produced according to the drinking water criterion. In order to comply with the Court's decision, however - from which it can be concluded that the Ctgb should make an effort to give an opinion on this point – and as provisional measure, to avoid a situation where no authorisation at all can be granted during the development of a model generation of the data necessary, the Ctgb has investigated whether the product under consideration and the active substance could give cause for concern about the drinking water criterion.

Sodium hypochlorite is on the market for more than 3 years (authorised before 1990).
From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case 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 under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

7.3.2 Atmosphere

Volatility of sodium hypochlorite strongly depends on the pH. At relevant pH conditions, alkaline to neutral, chemical species in sodium hypochlorite solution is dominated by OCl^-, which is slightly volatile.
AOPwin does not provide a half life calculation for sodium hypochlorite, therefore no information is

available on the trigger of < 2 days that is used as cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere.
Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. Therefore, effects on air quality only are taken into account when adverse effects are foreseen. The assessment of potential impacts on air quality, yet, is aimed to minimize the risk for stratospheric ozone depletion. Since there are no indications that sodium hypochlorite contributes to depletion of the ozone layer (no classification N; R59 Dangerous for the ozone layer), the environmental risk to air is considered acceptable.
The proposed applications meet the standards for air.

7.3.3 Terrestrial compartment

Soil organisms and non target arthropods (including bees)
For the proposed use there is no exposure of soil. The active substances will disappear through reaction with the excessive amount of organic material in the sewer system. Exposure of soil organisms and non target arthropods can therefore be excluded.
Proposed applications do not require assessment against the standards for soil organisms and non target arthropods.

Ground water
For the proposed use there is no direct exposure of soil. Therefore, no exposure of groundwater is expected.
Proposed applications do not require assessment against the standards for leaching to groundwater.

Persistence in soil
For the proposed use there is no direct exposure of soil. After emission to the sewer system the active substance will directly react and disappear. Considering the large reactivity of the active substance with organic matter (DT50 much smaller than criterion of 90 days), the accumulation of the active substance in soil can be excluded.
Proposed applications do not require assessment against the standards for persistence in soil.

7.3.4 Non compartment specific effects relevant to the food chain

Bioconcentration
Bioconcentration and secondary poisoning are no relevant processes for a strongly oxidative compound. The risk for bioconcentration in the proposed use is therefore considered not relevant.
The standards for bioaccumulation are met.

Primary and secondary poisoning of birds and mammals
A direct risk for birds and mammals is considered not relevant. The waste water will not contain hypochlorite or free chlorine after discharge to surface water because of the degradation processes that occur in the sewer system and the STP.
Also an indirect risk via secondary poisoning by the consumption of aquatic organisms or soil organisms is considered not relevant. Bioconcentration and secondary poisoning are no relevant processes for a strongly oxidative compound.
The standards for secondary poisoning of birds and mammals are met.

7.4 Overall conclusion
It can be concluded that:
1. the proposed applications of the active substance sodium hypochlorite meet the standards for aquatic and sediment organisms.
2. the proposed applications of the active substance sodium hypochlorite meet the standards for micro-organisms in STP
3. the proposed applications of the active substance sodium hypochlorite meet the standards for the production of drinking water from surface water.
4. the proposed applications of the active substance sodium hypochlorite does not require assessment against the standards for the production of drinking water from shallow groundwater.
5. the proposed applications of the active substance sodium hypochlorite meet the standards for the

air compartment.
6. the proposed applications of the active substance sodium hypochlorite does not require assessment against the standards for persistence in soil.
7. the proposed applications of the active substance sodium hypochlorite does not require assessment against the standards for soil organisms.
8. the proposed applications of the active substance sodium hypochlorite meet the standards for bioconcentration
9. the proposed applications of the active substance sodium hypochlorite meet the standards for primary and secondary poisoning of birds and mammals.
10. the proposed applications of the active substance sodium hypochlorite does not require assessment against the standards for non-target arthropods including bees.

Based on the available data, it can be concluded that the products Fink - FC 21, Fink Vetoplosmiddel, Cleaner PS-NF Super, Divosan TC 86, Premier Klercide-CR Sterile Biocide E, Reiclor, Hyproclor Plus and Calgonit DA Super containing the active substance sodium hypochlorite, when used in accordance with the proposed label (WG/GA) comply with the environmental standards and will not cause unacceptable effects on the environment.

Measures to protect the environment (risk mitigation measures)
No additional measures to protect the environment (risk mitigation measures) are required.

Data requirements
There are no additional data required.

7.5 Classification and Labelling
The current classification and labelling, which are prepared in conformity with Directive 1999/45/EC, can be maintained.

CONSULTED LITERATURE SOURCES

Ctgb dossier	The profile for sodium hypochlorite is based on earlier assessments of the a.s., available in C204.3.1 (6/4/09) and C197.3.1 (5/9/08).

H.8. Conclusion
When the products Fink - FC 21, Fink Vetoplosmiddel, Cleaner PS-NF Super, Divosan TC 86, Premier Klercide-CR Sterile Biocide E, Reiclor, Hyproclor Plus and Calgonit DA Super 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
The current classification and labelling, which are prepared in conformity with Directive 1999/45/EC, can be maintained.

H.10 References
No references are available.

Appendix I. Profile of active substance
The profile for sodium hypochlorite is based on earlier assessments of the a.s., available in C204.3.1 (6/4/09) and C197.3.1 (5/9/08).

Profiel milieuchemie en -toxicologie

Gedrag in grond
Gezien de grote reactiviteit van natriumhypochloriet ten opzichte van reducerende verbindingen en organische stof, alsmede door de overmaat van deze verbindingen in grond, zal het oxidant natriumhypochloriet bij emissies naar grond direct reageren en verdwijnen. Informatie over relevante reacties en omzettingsproducten staat hieronder beschreven in de paragraaf “Gedrag in water”.

Gedrag in water

Omzettingssnelheid en omzettingsroute in water

Natriumhypochloriet is in essentie een oplossing van chloor (Cl_2) in een oplossing van natronloog (NaOH). Chloor kan in water in drie verschillende chemische vormen voorkomen: als Cl_2 (chloor gas), HOCl (hypochlorig zuur) en OCl^- (hypochloriet ion). De verschillende reacties die kunnen optreden zijn hieronder weergegeven.

Als gasvormig chloor in aanraking komt met water ontstaat zoutzuur en hypochlorig zuur volgens reactievergelijking (1). Het evenwicht van deze reactie ligt aan de linkerkant:

$Cl_2 + H_2O \Leftrightarrow HCl + HOCl$ (1)

Wanneer Cl_2 wordt toegevoegd aan sterke basen zoals soda of kalk, verloopt de vorming van hypochlorig zuur in twee stappen volgens onderstaande vergelijking:

$2Cl_2 + 2OH^- \Leftrightarrow OCl^- + Cl^- + H_2O + Cl_2 \Leftrightarrow 2HOCl + 2Cl^-$ (2)

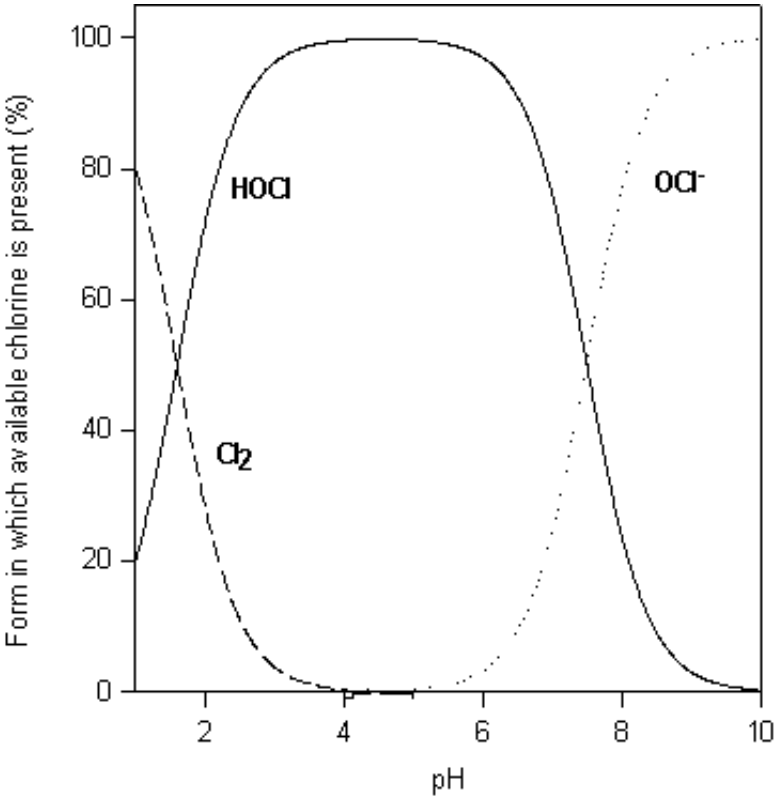
Bij de toevoeging van NaOCl of $Ca(OCl)_2$ aan water ontstaat hypochlorigzuur:

$NaOCl + H_2O \Leftrightarrow HOCl + NaOH$ (3)

$Ca(OCl)_2 + 2H_2O \Leftrightarrow 2HOCl + Ca(OH)_2$ (4)

Hypochlorig zuur is een zwak zuur dat gedeeltelijke dissociatie ondergaat volgens de vergelijking:

$HOCl \Leftrightarrow H^+ + OCl^-$ (5)



De vorm waarin chloor in water aanwezig is, is afhankelijk van de pH. In oplossingen met globaal pH < 4 is er een mengsel van Cl_2 en HOCl aanwezig. Tussen pH 4 en 11 is er een mengsel van HOCl en OCl^-, bij pH 7,5 is de ratio tussen OCl^- en HOCl gelijk aan 1. In sterk basische oplossingen ligt het evenwicht van vergelijking (3) geheel aan de linkerkant, boven pH 11 is al het chloor aanwezig als OCl^-. Hypochlorig zuur (HOCl) is een sterk reactieve verbinding en daarmee een sterkere disinfectans dat hypochloriet. Boven pH 11 neemt de biocidewerking van de oplossing dan ook af.

Twee andere reacties die kunnen optreden in verdunde waterige oplossingen zijn het uiteenvallen van

hypochlorig zuur tot chloraat en chloride (6), of tot zuurstof en chloride (7):

$3HOCl_{aq} \Leftrightarrow HClO_3 + 2HCl \Leftrightarrow 3H^+ + ClO_3^- + 2Cl^-$ (6)

$2HOCl_{aq} \Leftrightarrow O_2 + 2HCl \Leftrightarrow 2H^+ + 2Cl^- + O_2$ (7)

Beide reacties verlopen in het donker zeer langzaam. Decompositie is temperatuursafhankelijk en wordt bovendien versneld onder invloed van licht en de aanwezigheid van onzuiverheden (metalen). Deze reacties zijn de oorzaak van het afnemen van de concentratie actief chloor tijdens de opslag van de middelen. Een oplossing natriumhypochloriet van 150 g/l actief chloor, die opgeslagen wordt bij 15 °C in het donker, verliest in minder dan 3 maanden 1/6 deel van de concentratie werkzame stof.

Wanneer hypochloriet in contact komt met afvalwater treedt een groot aantal reacties op waarbij tal van (bij)producten kunnen ontstaan. Wanneer er stikstofhoudende verbindingen aanwezig zijn, worden chlooramines gevormd. Daarnaast kunnen langzame chloreringsreacties van organische moleculen (bijv. vluchtige vetzuren, humus- en fulvozuren) optreden, waarbij incorporatie van chloor plaatsvindt en gechloreerde organische microverontreinigingen ontstaan. Voorbeelden van gehalogeneerde organische bijproducten (organohalogen by-products; OBP) zijn chloroform, mono-, di- en trichloorazijnzuur en chloorfenolen. Bij de aanwezigheid van bromide in het oppervlaktewater, ontstaan bij het chloreren van zoet water bovendien gebromeerde microverontreinigingen en chloor/broomverbindingen. AOX (adsorbable organic halogens) is de somparameter voor de analyse van de totaal concentratie gehalogeneerde organische verbindingen. Uit onderzoek naar hypochlorietgebruik in huishoudens is gebleken dat ongeveer 1,5% van het chloor dat bij de toepassing wordt aangewend, wordt ingebouwd in gechloreerde organische bijproducten.

Binnen de chloorchemie worden verschillende termen gehanteerd om de concentratie actief chloor uit te drukken. Met het gehalte aan vrij chloor wordt de som van de gehalten opgelost Cl_2, HOCl en OCl^- bedoeld (bij pH>4 is dit alleen HOCl/OCl^-). De concentratie vrij chloor wordt uitgedrukt als mg Cl_2/L. Totaal chloor bevat naast vrij chloor, ook de fractie gebonden chloor (chlooramines, maar ook andere oxidatieproducten). Totaal chloor en gebonden chloor worden eveneens uitgedrukt als mg Cl_2/L.

Gedrag in lucht

Omzettingssnelheid en omzettingsroute in lucht

Er zijn geen gegevens over omzettingssnelheid en effecten van hypochloriet (ClO^-) in de atmosfeer. Het middel op basis van natriumhypochloriet bevat een sterk alkalische oplossing. Hypochloriet is bij hoge pH de dominante verbinding en deze verbinding is niet vluchtig. De fractie ongedissocieerd HOCl heeft een zekere vluchtigheid, maar bij de hoge pH van de gebruiksoplossing is de fractie HOCl verwaarloosbaar klein. Bij pH waarden >8 zullen chlooramines, reactieproducten van NH_3 met natriumhypochloriet, de belangrijkste vluchtige verbindingen zijn.
In de RAR worden de volgende waarden gemeld:

ClO-	pH = 8.5	H = 0.07 10^{-4}
HOCl	pH = 5.5	H = 0.4 10^{-4}

Gedrag in water

Omdat hypochloriet wordt geloosd op het riool, zijn de reacties die in afvalwater kunnen optreden van belang. In het riool zal het actief chloor worden omgezet. De snelheid waarmee dat gebeurt is groot (halfwaardetijd van enkele minuten). Over het algemeen zullen hierbij eerst snelle oxidatiereacties optreden met eenvoudig te oxideren anorganische stoffen (Fe^{2+}, Mn^{2+}, e.d.), waarbij chloride ontstaat. Vervolgens treden reacties met anorganische en organische stikstofverbindingen op onder vorming van chlooramines en organische chloorstikstofverbindingen. Verder is sprake van langzame oxidatie van organische verbindingen en van incorporatie van chloor met als bijproduct gechloreerde organische microverontreinigingen, zoals bijvoorbeeld trihalomethanen (THM) en gehalogeneerd azijnzuur en gehalogeneerde humusverbindingen. Geschat wordt dat de concentraties van deze verbindingen na verdunning in het afvalwater in de orde van µg/L liggen. Door de omzettingsreacties die optreden in het afvalwater, zal het afvalwater bij het bereiken van de RWZI normaliter geen hypochloriet of vrij chloor bevatten. De gechloreerde organische bijproducten, in een kleine hoeveelheid gevormd bij de toepassing van hypochloriet, zijn voor een belangrijk deel biologisch afbreekbaar en vaak ook vluchtig met de verwachting dat deze uitgeblazen worden tijdens het verblijf in de RWZI. Wanneer hypochloriet

in contact komt met mest, treedt een keten van reacties op die in route en snelheid vergelijkbaar zijn met het gedrag van de w.s. in het riool.

Effecten op de biologische afvalwaterzuivering:
Zie voor een overzicht van de toxiciteit van hypochloriet voor actief slib Tabel M.2.

Tabel M.2. Overzicht van toxiciteit van natriumhypochloriet voor micro-organismen in RWZI

Teststof	Proces	EC50 [mg/L]	Opmerkingen
Natriumhypochloriet	RWZI, actief slib	3	Continue blootstelling

De biomassa in actief slib blijkt minder gevoelig voor hypochloriet als op basis van de bactericide werking van het middel verwacht kan worden. Dit kan verklaard worden door het feit dat de biomassa is ingebed in een slibvlok, die naast biomassa bestaat uit exopolymeren met ingevangen organisch en anorganisch materiaal.

De gevoeligheid van actief slib bij blootstelling aan hypochloriet blijkt afhankelijk van de slibconcentratie gedurende de proef.

Toxiciteit voor aquatische organismen:
Ecotoxicologische data voor hypochloriet zijn met name beschikbaar in de openbare literatuur. In de RAR van RMS Italië (november 2007) wordt op basis van openbare literatuur een overzicht wordt gegeven van de beschikbare eindpunten met betrekking tot de toxiciteit voor aquatische organismen, zie onderstaande tabel.

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)
Crustacean (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)
Crustacean	-		-	
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

In aanvulling op bovenstaande kan worden vermeld dat door het RIZA in het kader van een studie naar de aquatische toxiciteit van koelwater op basis van interne gegevens een ad hoc MTR is afgeleid van 0,3 μg vrij chloor/L.

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[1] In the summary of the RAR erroneously indicated as 24 available chlorine mg/kg bw/d.