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Sitech IAZI bv

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Derivation of the indicative Drinking Water Target Value for two biopolymers

TECHNICAL REPORT

Report for

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Document revisions

No.	Details	Date
R10-1	Internal draft	2020-12-14
R10-2	First draft report	2021-01-21
R10-3	Final report	2021-04-21

Executive Summary

Wood was retained by Sitech IAZI bv to derive substance specific drinking water target value for two biopolymers: Na-CMI (CAS# 430439-54-6) and Na-CMS (CAS# 9063-38-1) using the formal guidance documents. Before mentioned biopolymers are important ingredients in conditioning agents used to protect the proper functioning of industrial water systems like cooling systems and filtration units.

Sitech IAZI bv requests the Wetenschappelijke Klankbordgroep normstelling water en lucht to evaluate and approve the proposed drinking water target values for the two biopolymers as summarized in below table.

Proposed drinking water target values

Substance	Proposed DTV in mg/L
Sodium salt of carboxymethyl inulin (Na-CMI, CAS# 430439-54-6)	12
Sodium salt of carboxymethyl starch (Na-CMS, CAS# 9063-38-1)	58

Please note that in this report a comma is used as decimal separator as defined in the methodology to derive (indicative) environmental quality standards [RIVM, 2015]. A point is used as a thousand separator as appropriate.

Contents

1. Introduction

Sitech IAZI bv, hereafter Sitech, operates a wastewater treatment plant at the Industrial Park Chemelot, hereafter referred to as IAZI. The IAZI receives and treats most of the wastewater generated at the site, including purges from cooling water systems and filtration units. Before mentioned purges contain cooling water conditioning chemicals, like biocides, dispersants and anti-fouling agents.

Present wastewater discharge permit holds an obligation to minimize the use of the dispersant ATMP (CAS# 6419-19-8) in order to prevent the generation of AMPA (CAS# 74341-63-2) in the IAZI due to biodegradation of ATMP. As AMPA is a persistent chemical, one of the adverse effects of the discharge with the effluent is potential exceedance of the limit value for the intake of surface water for the preparation of drinking water.

Over the past years, Sitech has investigated potential alternatives to replace ATMP as a cooling water dispersant. Products comprising biopolymers such as carboxymethyl starch (CMS, CAS# 9063-38-1) and or carboxymethyl inulin (CMI, CAS# 430439-54-6) are listed as potential alternatives for ATMP.

The potential impact of the discharge of (sodium salts of) CMS and CMI with the effluent of the IAZI on the functions of the receiving water body, like any other discharge of chemical contaminants, needs to be assessed according to the so-called immissietoets (discharge test). In the underlying situation the potential adverse effects of the discharge in regard to aquatic ecology and the drinking water preparation functions are relevant.

The Dutch National Institute for Public health and the Environment compiled a formal guidance on the derivation of substance specific drinking water parameters [RIVM, 2017] which aligns with the procedures of the European Commission. The European Commission published an update of the Guidance Document in 2018 [EC, 2018].

Wood was asked by Sitech to derive substance specific water quality standards for the sodium salts of CMS and CMI using the formal guidance documents. This report describes results of literature research and proposes values for water quality standards for both substances.

Please note that in this report a comma is used as decimal separator as defined in the methodology to derive (indicative) environmental quality standards [RIVM, 2015]. A point is used as a thousand separator as appropriate.

2. Generic approach to derive water quality standards

2.1 Drinkwater target value

The procedure to calculate a substance specific drinking water target is described in RIVM report 2017-0091 [RIVM, 2017] in concordance with Guidance Document No. 27 [EC, 2018]. The drinking water target value is calculated from the Derived No Effect Level Tolerable, DNEL, or the Tolerable Daily Intake (TDI) using below formula:

$$DTV = \frac{BW * DNEL * \max\_fraction}{DI}$$

with

DTV =	drinking water target value (mg/L)
BW =	average body weight (= 70 kg)
DNEL =	Derived No Effect Level, like the Tolerable Daily Intake in mg per kg body weight per day or the Acceptable Daily Intake in mg per kg body weight per day
max_fraction =	Maximum uptake as a percentage of the DNEL (20%)
DI =	Average daily water consumption (= 2 L / day)

Resulting in

$$DTV = \frac{70 * DNEL * 20\%}{2} = 7 * DNEL$$

Appendix D presents flow diagrams to derive drinking water target values as set by RIVM guidance [RIVM, 2017].

3. Stepped derivation of the drinking water target value for the sodium salts of Na-CMS and Na-CMI

Biopolymers are, amongst others, used as a water treatment agent to control the fouling of amongst other, industrial cooling systems. Products comprising biopolymers can be suitable to replace agents based on organic phosphates which are traditionally used for this purpose.

The underlying biopolymers consist of the sodium salt of carboxylated inulin (Na-CMI) and or the sodium salt of carboxylated starch (Na-CMS).

To derive a drinking water target value, a literature search was executed regarding Na-CMS and Na-CMI using CAS# 9063-38-1 and CAS# 430439-54-6 respectively. These substances are active components of conditioning / cleansing products which are used at the Industrial Site Chemelot at Geleen, the Netherlands. Appendix A presents available base information for these substances.

Appendix B and Appendix C present the results of a literature search for Na-CMI and Na-CMS respectively. For both substances, a specific drinking water target value is derived. A summary of the relevant properties of both substances is presented in table 3.1.

Table 3.1 Summary of relevant toxicological data for Na-CMI and Na-CMS

Parameter	Na-CMI	Na-CMS
LD50 oral Rat	No references found	No references found
Skin irritation	Not indicated	No references found
Eye irritation	No references found	No references found
Skin sensitization	No references found	No references found
Repeated dose toxicity oral (NOAEL)	1.000 mg/kg-bw/day	5.000 mg/kg-bw/day
Genetic toxicity (in vitro)	No references found	No references found
Genetic toxicity (in vivo)	Not indicated	Not indicated
Reproductive toxicity (NOEL)	Not indicated	Not indicated

Based on the data in table 3.1 the DNEL for Na-CMS and Na-CMI are derived from the NOAEL for repeated dose toxicity oral. The results are presented in table 3.2.

Table 3.2 Derivation of the DNEL for Na-CMI and Na-CMS

Parameter	Na-CMI	Na-CMS
NOAEL	1.000 mg/kg-bw/day	5.000 mg/kg-bw/
Assessment factors		
Subacute to chronic duration	6	6
Rat to human	10	10
Intraspecies variability	10	10
DNEL	1,67 mg/kg-bw/day	8,33 mg/kg-bw/day

The drinking water target value is derived from the calculated DNEL using below formula. The derived values are presented in table 3.3.

$$DTV = \frac{BW * DNEL * \max\_fraction}{DI} = 7 * DNEL$$

Table 3.3 Derivation of the drinking water target value for Na-CMS and Na-CMI

Parameter	Na-CMI	Na-CMS
DNEL	1,67 mg/kg-bw/day	8,33 mg/kg-bw/day
DTV	11,7 mg/L	58,3 mg/L

4. Discussion

The above derived drinking water target values for Na-CMS and Na-CMI indicate that these substances are of limited risk to human health regarding exposure through drinking water. This result is in line with the use of the two substances as a food additive and as disintegrant in pharmaceuticals and dietary products. Rounded to two digits the derived drinking water target values for Na-CMI and Na-CMS amount 12 mg/L and 58 mg/L respectively.

In order to monitor the ultimate discharge of the Na-CMI and Na-CMS to surface water, Sitech IAZI BV, the operator of the wastewater treatment plant (IAZI) at the Industrial park Chemelot, together with the suppliers of these and similar (bio)polymers, recently started the development of a protocol for the analysis of biopolymers in the effluent of the wastewater treatment plant from scratch. As at this stage several base analytical methodologies are reviewed.

The main functionality of the evaluated biopolymers is to bind and disperse bivalent cations, like Calcium and Magnesium, in order to prevent scaling in industrial water systems. Discharged amounts of the polymer will behave in a similar manner in surface water and the water treatment facilities drinking water companies apply in the production of drinking water. Treatment systems used for the production of drinking water from surface water typically comprise sand filtration and activated carbon adsorption. This implies that sodium salts of CMS and CMI present in surface water used for the preparation of drinking water will be removed to a certain extent, thus further reducing potential risk for public health.

Both Na-CMI and Na-CMS are used as food additives. The base backbone of these substances are fructose and glucose respectively. Public sources on the internet state that Inulin powders have a bland to subtly sweet taste. Starch powder basically is deemed to taste bland.

In Appendix E further information is presented regarding the organoleptic properties of Na-CMI and Na-CMS. Executed experiment with these substances in concentrations equal to the derived drinking water target values shows that there is no impact on the colour of the solution.

Drinking water prepared from extracted surface water will be subject to treatment, reducing the concentration of Na-CMI and Na-CMS. It is anticipated that the taste of drinking water prepared from surface water containing Na-CMI or Na-CMS up to concentrations equal or less than the derived drinking water target values, is not adversely affected.

5. Proposed substance specific drinking water target values

Below table presents an overview of the proposed drinking water target values.

Table 5.1 Proposed drinking water target values

Substance	DTV in mg/L
Na-CMI (CAS# 430439-54-6)	12
Na-CMS (CAS# 9063-38-1)	58

6. References

EC, 2018. "Technical Guidance for Deriving Environmental Quality Standards"; Guidance Document No. 27, updated version 2018.

Min IenW, 2019. "Handboek immissietoets, versie 2019"; Ministerie van Infrastructuur en Milieu, Rijkswaterstaat; concept document versie oktober 2019.

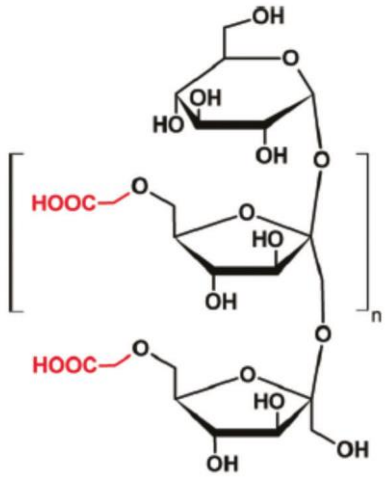
RIVM, 2015. "Handleiding voor de afleiding van indicatieve milieurisicogrenzen"; RIVM Rapport 2015-0057, L.R.M. de Poorter et al, RIVM Centrum voor Veiligheid van Stoffen en Producten.

RIVM, 2017. "Evaluatie signaleringsparameter nieuwe stoffen drinkwaterbeleid"; RIVM Rapport 2017-0091, N.G.F.M. van der Aa et al, RIVM Centrum voor Veiligheid van Stoffen en Producten.

Appendix A
Base information Na-CMS (CAS# 430439-54-6) and Na-CMI (CAS# 9063-38-1)

Na-CMI (CAS# 430439-54-6)

Identification and classification

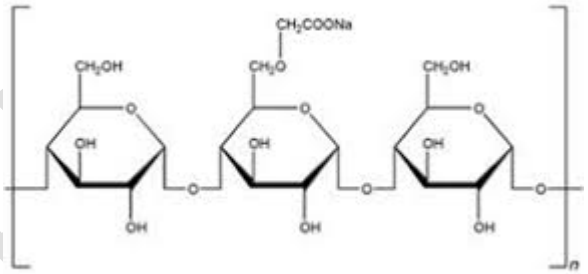
Name	Sodium carboxymethyl inulin
IUPAC-name	Sodium carboxymethyl inulin
Synonyms	Na-CMI (or just CMI) Carboxymethyl ether Carboxyline
CAS-number	430439-54-6 (Sodium salt) 9005-80-5 (protonated)
Chemical group according to EPIwin	Biopolymers
Cramer class	Not applicable
Known uses	Dispersant to control fouling in industrial water systems
Toxicity mechanism	-
Harmonized classification	TBD
Molecule formula	$[C_2H_4O_3.Na]n$
Smiles	-
Molecule structure ¤	

Fysico-chemical properties and dispersion

Property	Value	Additional information	Reference
Molecular weight (g/mol)	No data		
Melting point (°C)	No data		
Boiling point (°C)	No data		
Vapour pressure (Pa)	No data		
Solubility in water (mg/L)	Complete		
Log K_{ow}	<0		Expert judgement
Henry-coëfficiënt (Pa m^3/mol)	No data		
pKa	No data		

Na-CMS (CAS# 9063-38-1)

Identification and classification

Name	Sodium carboxymethyl starch
IUPAC-name	Sodium carboxymethyl starch
Synonyms	Na-CMS (or just CMS) Sodium starch glycolate
CAS-number	9063-38-1
Chemical group according to EPIwin	Biopolymers
Cramer class	Not applicable
Known uses	Dispersant to control fouling in industrial water systems
Toxicity mechanism	-
Harmonized classification	TBD
Molecule formula	$[C_2H_4O_3 \cdot Na]n.$
Smiles	-
Molecule structure	

Fysico-chemical properties and dispersion

Property	Value	Additional information	Reference
Molecular weight (g/mol)	No data		
Melting point (°C)	No data		
Boiling point (°C)	No data		
Vapour pressure (Pa)	No data		
Solubility in water (mg/L)	Complete		
Log K_{ow}	<0		Expert judgement
Henry-coëfficiënt (Pa m^3/mol)	No data		
pKa	No data		

Appendix B
Derivation of the Drinking water Target Value for the Sodium salt of Carboxymethyl Inulin (Na-CMI)

Summary

The toxicological profile of carboxymethyl inulin drafted by Johanssen [2013] has been used as the basic document for toxicity information. The lowest NOAEL was selected from a range of toxicological endpoints in studies with rodents. The lowest NOAEL was found to be 1.000 mg/kg-bw/day related to the oral feed study for a period of 4 weeks in rats. This NOAEL was taken as starting point for deriving a maximum concentration in drinking water. For deriving a DNEL (Derived No Effect Level) of CMI for the general population, the following assessment factors were considered:

- subacute to chronic duration (6)
- interspecies variability (10)
- intraspecies variability (10)

Applying above assessment factors to the lowest NOAEL results into a DNEL for the general population of (1.136/(6*10*10) =) 1,67 mg/kg-bw/day. In addition, the daily dose via drinking water uptake (2 litres at 70 kg bodyweight per day) may not exceed 20% of the DNEL of the general population.
This results in a drinking water limit of (20%*70*1,67/2 =) 11,7 mg CMI per litre.

1. Introduction

Carboxymethyl inulin (CMI) belongs to the category of biopolymers. CMI is a water-soluble polysaccharide extracted from plants like chicory and beetroots. CMI a which is widely used as a dietary fibre ingredient to improve food quality. As the molecule is biodegradable and non-toxic, CMI containing products also are finding an increasing number of applications in the paper and pulp industry, textile fabrication and the exploration of oil and gas.

If the carboxylic groups are occupied by an H^+-ion, the aqueous solution has a low pH. If all carboxylic groups contain a Na^+-ion, e.g. Na-CMI, the pH is about neutral. The backbone of CMS is shown in figure 1.

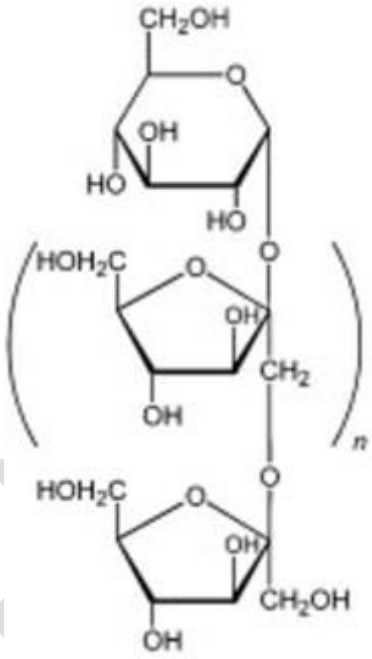


Fig. 1 Backbone of CMI

As result of using Na-CMI / CMI containing products in industrial processes, discharges of wastewater into surface water may contain (Na-)CMI. Surface water can be used as a raw material for the preparation of drinking water. The technical processes for the preparation of drinking water are not always able to remove (sodium salts of) CMS completely from the extracted surface water.
This note reviews the existing toxicological information of CMI with the aim to derive a limit for this component in drinking water.

2. Toxicological information regarding carboxymethyl inulin

The toxicology of CMI is extensively investigated as the substance is widely used as a food additive. Referencing to the hazard classification and labelling of CMI, the ECHA website states that "according to the majority of notifications provided by companies to ECHA in CLP notifications, no hazards have been classified". The toxicological findings have been summarized in the following paragraphs.

2.1 Acute oral toxicity (rat)

No references found to this type of study.

2.2 Acute dermal toxicity(rabbit)

No references found to this type of study.

2.3 Acute inhalation toxicity (LC50 4 hours)

No references found to this type of study.

2.4 Skin Irritation

No references found to this type of study.

2.5 Skin sensitisation

No evidence of dermal sensitization was observed in groups of guinea pigs following CMI testing by the Magnusson-Kligman maximization test methodology [Johanssen, 2013].

2.6 Repeated dose toxicity (oral)

Johannsen [2003] investigated the toxicity of CMI following repeated exposure via gavage. Subacute four-week oral toxicity was investigated in groups of rats exposed via gavage to 0, 50, 150 and 1.000 mg CMI/kg-bw.day. No treatment-related effects were observed in body weight, food consumption, mortality, hematology, clinical blood chemistry, organ weights or gross or microscopic pathology up to the highest dose (1.000 mg/kg/day) tested.
Motor activity, as observed in a functional observation battery, was elevated in high-dose females, and is not considered of significance toxicologically.
Lack of adverse toxicity seen with CMI at dosages up to 1.000 mg CMI/kg-bw.day is consistent with a similar lack of significant toxicity exhibited by other dietary carbohydrates (sorbitol, sucrose, glucose), oligofructoses (inulin/FOS) and carboxylated inulin in repeated-dose rat studies at approximately the same dosage [Johanssen, 2013].

2.7 Repeated dose toxicity by inhalation

No references found to this type of study.

2.8 Repeated dose toxicity by dermal exposure (bath water)

No references found to this type of study.

2.9 Genetic toxicity in vitro

No references found to this type of study. Genetic toxicity is not indicated by Toxtree.

2.10 Genetic toxicity in vivo

No mutagenic activity was observed when CMI was tested in four Salmonella strains-TA1535, TA1537, TA98

and TA100-or in Escherichia coli WP2uvrA bacterial point mutation assays or in an in vitro Chinese hamster ovary cell chromosomal aberration assay [Johanssen, 2013]. The results obtained in the present study with CMI are consistent with similar data derived on numerous dietary carbohydrate fibers generally recognized as safe in the human diet.

2.11 Carcinogenicity

No references found to this type of study. Carcinogenicity is not indicated by Toxtree.

2.12 Reproductive and developmental toxicity

No references found to this type of study.

3. Derivation of the Drinking water Target Limit for CMI

In the 28-day repeated dose study in rats the highest dose without any effect appeared to be 1.000 mg/kg-bw/day, based on the repeated dose oral toxicity.

In the ECHA Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health (Version: 2.1 November 2012) has been stated how such an acute NOAEL should be translated to a Derived No Effective Level for consumers via extrapolation assessment factors:

rat to human	10
general population	10
28 days to 2 year rat	6

This results into a DNEL of 1.000 / (10*10*6) = 1,67 mg CMI/kg-bw/day for humans.

There is an additional limitation in the Netherlands for drinking water. Drinking water may not contribute more than 20% of the total DNEL to the daily body burden in a daily drinking water volume of 2 litres at a body weight of 70 kg. This means that the total concentration of CMI in drinking water may not exceed 20%*70*1,67/2 = 11,7 mg/litre.

4. References

Johannsen, F.R, 2003. "Toxicological profile of carboxymethyl inulin"; Food Chem. Toxicity, Vol 41 (1), pp. 49 – 59; January 2003

Toxtree. "Estimation of Toxic Hazard – A Decision Tree Approach"; version 3.1.0.1851, www.ideaconsult.net.

Appendix C
Derivation of the Drinking water Target Value for the Sodium salt of Carboxymethyl Starch (Na-CMS)

Summary

An EPA report on the sodium salt of carboxymethyl starch has been used as the basic document for toxicity information. The lowest NOAEL was selected from a range of toxicological endpoints in studies with rodents. The lowest NOAEL was set at 5.000 mg/kg-bw/day related to the oral feed study for a period of 3 weeks in rats. This NOAEL was taken as starting point for deriving a maximum concentration in drinking water. For deriving a DNEL (Derived No Effect Level) of Na-CMS for the general population, the following assessment factors were considered:

- subacute to chronic duration (6)
- interspecies variability (10)
- intraspecies variability (10)

Applying above assessment factors to the lowest NOAEL results into a DNEL for the general population of (5.000/(6*10*10) =) 8,33 mg/kg-bw/day. In addition, the daily dose via drinking water uptake (2 litres at 70 kg bodyweight per day) may not exceed 20% of the DNEL of the general population.
This results in a drinking water limit of (20%*70*1,88/2 =) 58,3 mg Na-CMS per litre.

1. Introduction

Carboxymethyl starches (CMS) belong to the category of biopolymers. CMS are a water-soluble polysaccharide which is widely used as an additive in medicine. As the molecule is biodegradable and non-toxic, CMS containing products also are finding an increasing number of applications in the paper and pulp industry, textile fabrication and the exploration of oil and gas.

If the carboxylic groups are occupied by an H^+-ion, the aqueous solution has a low pH. If all carboxylic groups contain a Na^+-ion, the pH is about neutral. The backbone of CMS is shown in figure 1.

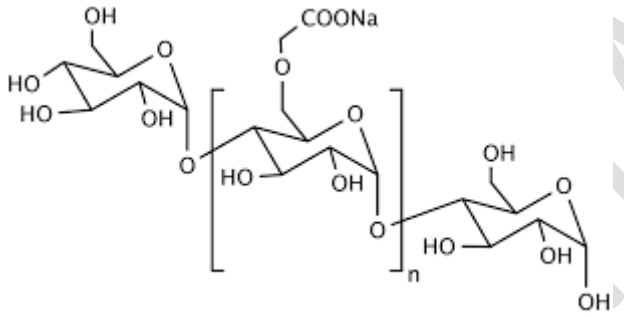


Fig. 1 Backbone of CMS

As result of using CMS containing products in industrial processes, discharges of wastewater into surface water may contain CMS. Surface water can be used as a raw material for the preparation of drinking water. The technical processes for the preparation of drinking water are not always able to remove CMS completely from the extracted surface water.
This note reviews the existing toxicological information of (Na-)CMS with the aim to derive a limit for this component in drinking water.

2. Toxicological information regarding carboxymethyl starch

The toxicology of Na-CMS is extensively investigated as the substance is widely used in pharmaceuticals and dietary disintegrants. Referencing to the hazard classification and labelling of Na-CMS, the ECHA website states that "according to the majority of notifications provided by companies to ECHA in CLP notifications, no hazards have been classified". The toxicological findings have been summarized in the following paragraphs:

2.1 Acute oral toxicity (rat)

No references found to this type of study.

2.2 Acute dermal toxicity(rabbit)

No references found to this type of study.

2.3 Acute inhalation toxicity (LC50 4 hours)

No references found to this type of study.

2.4 Skin Irritation

No references found to this type of study.

2.5 Skin sensitisation

No references found to this type of study.

2.6 Repeated dose toxicity (oral)

A 21-day rat feeding study was conducted by the Central Institute for Nutrition and Food Research [TNO, 1963] using a modified starch compound that is very similar to sodium starch glycolate (Na-CMS). Rats were fed diets that contained 60% wheat starch (control), 20%, 40%, or 60% of the modified starch. TNO summarized the study as follows: It "appears that good growth occurred on rations with 20% modified starch, although slight loss of hair was observed; 40% modified starch supported good growth but caused loss of hair and slight diarrhea; 60% modified starch caused slight growth retardation, moderate diarrhea and loss of hair and distinctly increased water intake."
In 1993, in correspondence dated July 29, TNO discussed the 1963 21-day rat feeding study. The reviewer indicated sodium starch glycolate would be well-tolerated at a level of 5% which would correspond to a daily intake of about 5 g/kg body weight.

2.7 Repeated dose toxicity by inhalation

No references found to this type of study.

2.8 Repeated dose toxicity by dermal exposure (bath water)

No references found to this type of study.

2.9 Genetic toxicity in vitro

No references found to this type of study.

2.10 Genetic toxicity in vivo

No references found to this type of study. Genetic toxicity is not indicated by Toxtree.

2.11 Carcinogenicity

No references found to this type of study. Carcinogenicity is not indicated by Toxtree.

2.12 Reproductive and developmental toxicity

No references found to this type of study.

3. Derivation of a drinking water limit for Na-CMS

In the 21-day repeated dose study in rats the highest dose without any effect appeared to be 5.000 mg Na-CMS/kg-bw/day, based on the repeated dose oral toxicity.

In the ECHA Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health (Version: 2.1 November 2012) has been stated how such an acute NOAEL should be translated to a Derived No Effective Level for consumers via extrapolation assessment factors:

rat to human	10
general population	10
28 days to 2 year rat	6

This results into a DNEL of 5.000 / (10*10*6) = 8,33 mg Na-CMS/kg-bw/day for humans.

There is an additional limitation in the Netherlands for drinking water. Drinking water may not contribute more than 20% of the total DNEL to the daily body burden in a daily drinking water volume of 2 litres at a body weight of 70 kg. This means that the total concentration of Na-CMS in drinking water may not exceed 20%*70*8,33/2 = 58,3 mg/litre.

4. References

EPA, 2002. "Sodium Starch Glycolate; Proposed Exemption From the Requirement of a Tolerance"; Environmental Protection Agency; Document 40 CFR Part 180, Federal Register / Vol. 67, No. 12; January 17, 2002

Toxtree. "Estimation of Toxic Hazard – A Decision Tree Approach"; version 3.1.0.1851, www.ideaconsult.net.

Appendix D
Flowcharts for the derivation of the TDI

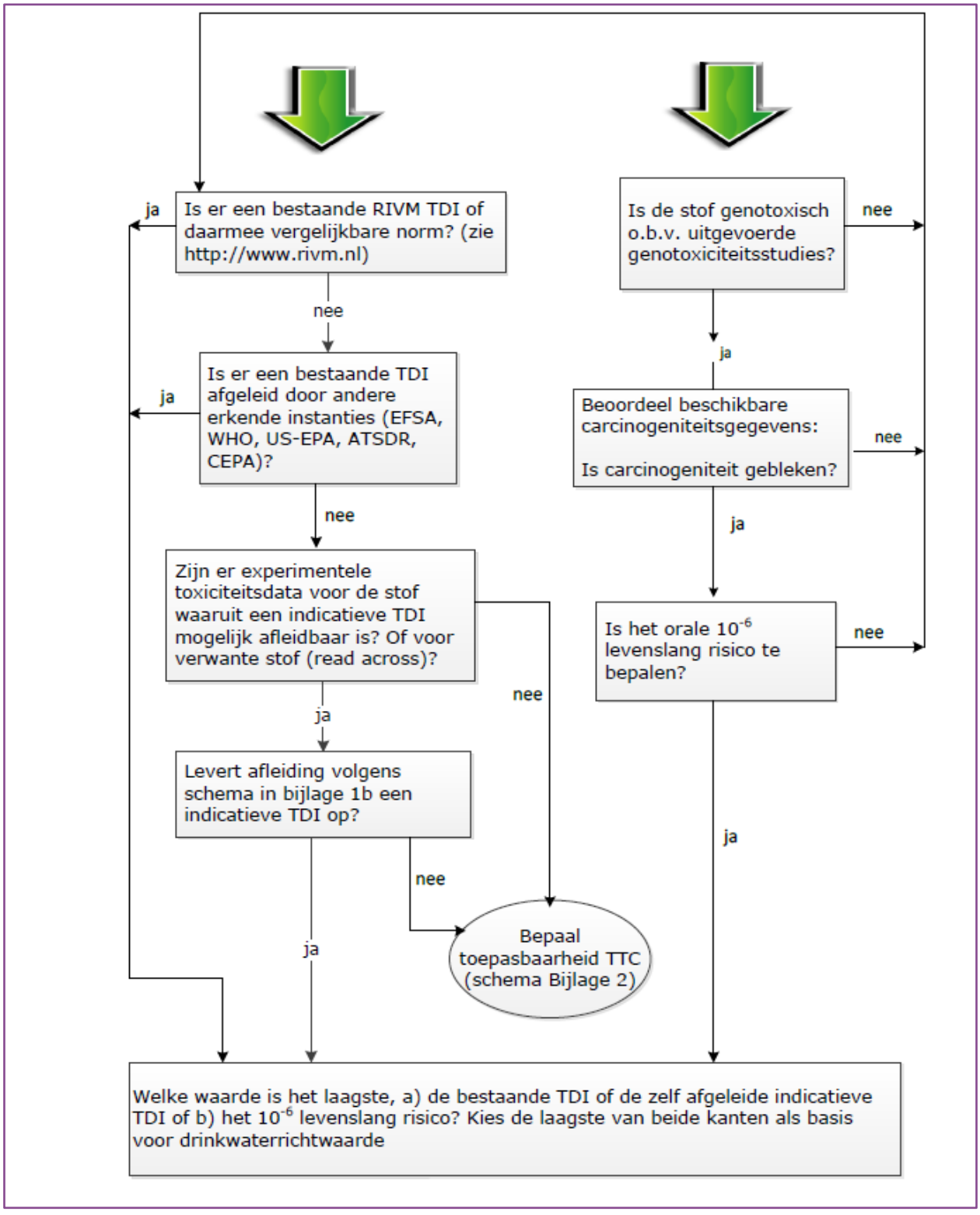


Figure D.1 Flow diagram to determine the necessity of derivation of the TDI

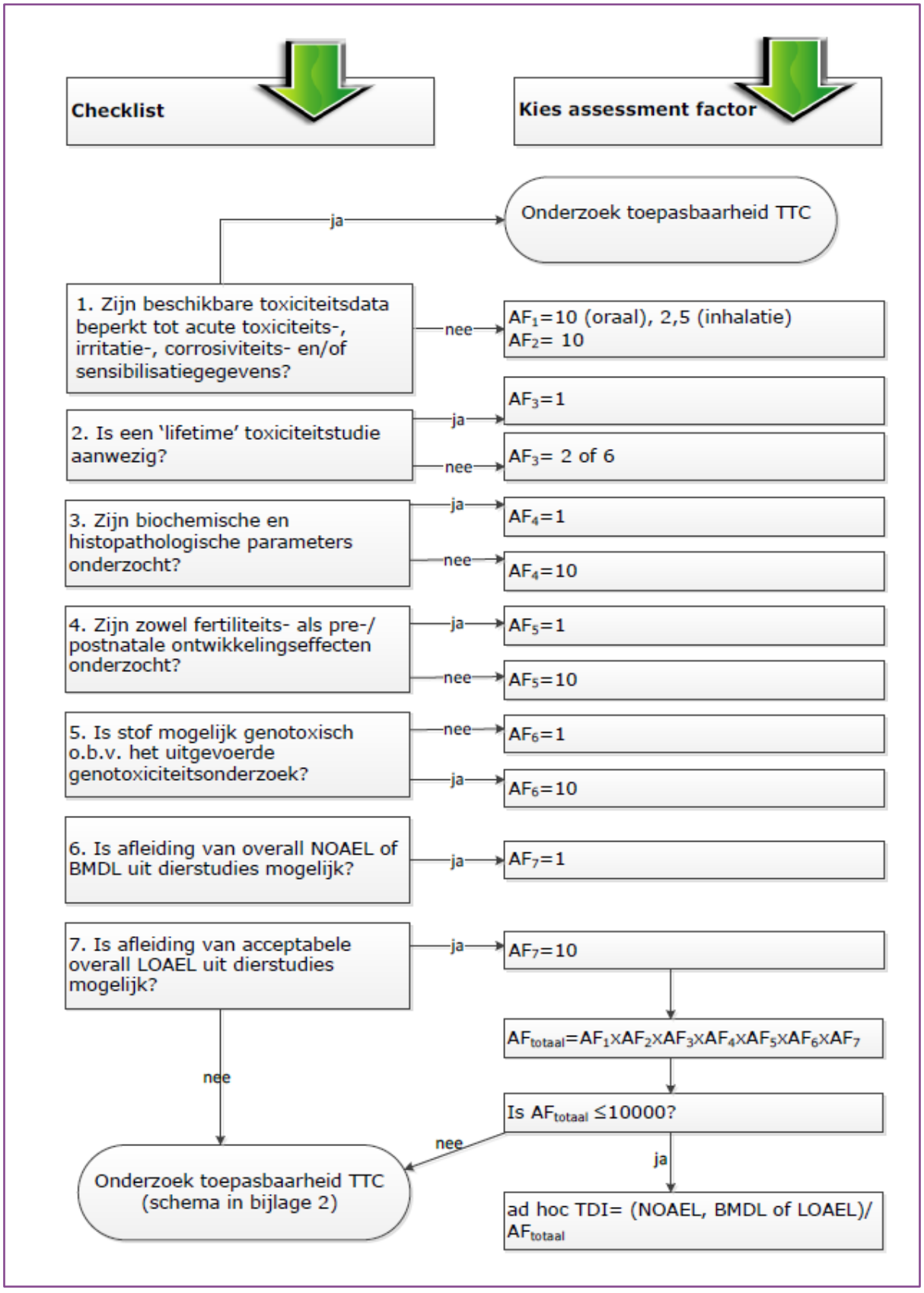


Figure D.2 Flow diagram to derive the TDI for a chemical using assessment factors

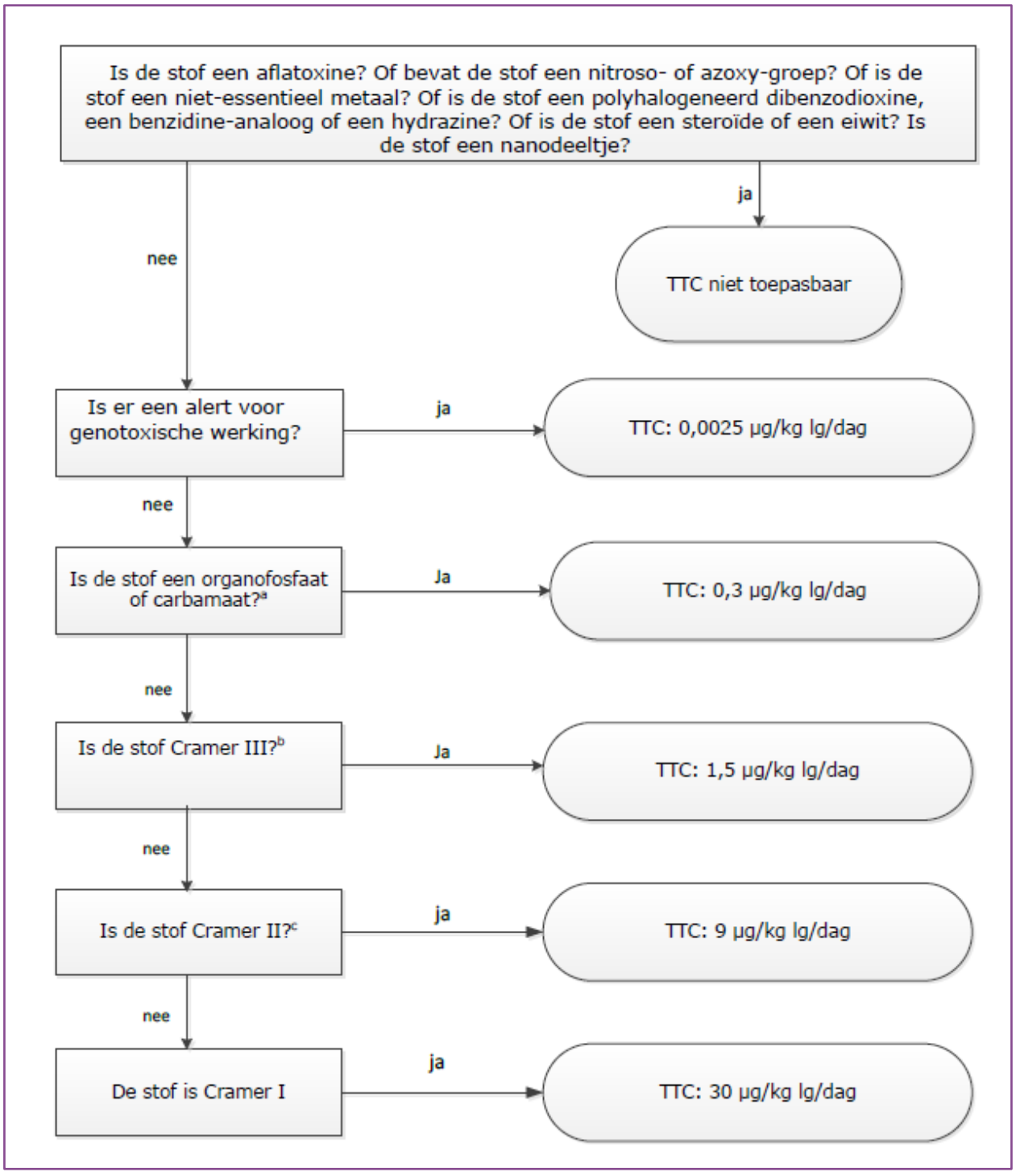


Figure D.3 Flow diagram to derive the TDI based on generic properties

Appendix E
Organoleptic properties of Na-CMI and Na-CMS at derived drinking water target values

Resultaten / Waarnemingen

Er zijn twee oplossingen gemaakt:
- Een oplossing met 20 mg/L CMI in leidingwater
- Een oplossing met 58 mg/L CMS in leidingwater

Figuur 1 links: oplossing CMI (20 mg/L), midden: leidingwater, rechts: oplossing CMS (58 mg/L)

Van de beide oplossingen is de troebelheid (in FAU) en de kleur (in Pt-Co) bepaald ten opzichte van leidingwater.

Troebelheid CMI oplossing: 0 FAU
Troebelheid CMS oplossing: 0 FAU

Kleur CMI oplossing: 0 Pt-Co
Kleur CMS oplossing: 0 Pt-Co

Conclusie / Discussie

Er zit geen verschil tussen de drie oplossingen zowel visueel als in troebelheid en kleur.

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