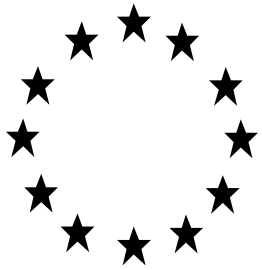
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Tolylfluanid

Product-type 21
(Antifouling products)

June 2014

Finland

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance tolylfluanid as product-type 21 (Antifouling products), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Tolylfluanid (CAS no.731-27-1) was notified as an existing active substance, by Lanxess Deutschland GmbH, hereafter referred to as the applicant, in product-type 21.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

In accordance with the provisions of Article 7(1) of that Regulation, Finland was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for tolylfluanid as an active substance in Product Type 21was 31 March 2006, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 30 March 2006, Finnish competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 31 July 2006.

On 18 September 2012, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Agency. Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of tolylfluanid for product-type 21, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site shall be taken into account.

[1] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

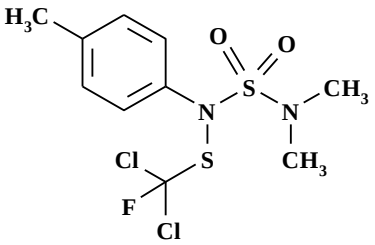
However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity

CAS-No	731-27-1
EINECS-No.	211-986-9
Other No. (CIPAC, ELINCS)	CIPAC No. 275
IUPAC Name	N-(Dichlorofluoromethylthio)-N',N'-dimethyl-N-p-tolylsulfamide
C.A. Name	Methanesulfenamide, 1,1-dichloro-N-[(dimethylamino)sulfonyl]-1-fluoro-N-(4-methylphenyl)-
Common name,	Tolylfluanid
Synonyms	KUE 13183 B
	Preventol A5-S
	Euparen M
	Preventol A 5
	Preventol VPOC 3017
Molecular formula	$C_{10}H_{13}Cl_2FN_2O_2S_2$
Structural formula	
SMILES	CN(C)S(=0)(=0)N(SC(F)(CL)CL)c1ccc(C)cc1
Molecular weight (g/mol)	347.3
Minimum purity	960 g/kg

Physico-Chemical Properties

Tolylfluanid is a solid substance (colourless crystalline powder, technical active ingredient, or colourless crystals, purified a.i.) with a melting point of 93 °C. The substance decomposes before boiling at 200 °C. It is only slightly volatile, with a vapour pressure of $2 \bullet 10^{-4}$ Pa (at 20 °C, by extrapolation) and Henry's law constant of $6.6 \bullet 10^{-2}$ Pa•m^3/mol. Tolylfluanid does not absorb visible or ultraviolet light above 290 nm. The water solubility is slight (1.04 mg/l at 20 °C and pH 4), and is independent of the pH. The value of pK could not be determined. The log K_{ow} is 3.9 at 20 °C. The solubility of tolylfluanid in acetone, acetonitrile, dichloromethane, dimethylsulfoxide, and ethylacetate exceeds 250 g/l, and the substance is readily or highly soluble other solvents tested; 1-octanol (16 g/l), 2-propanol (22 g/l), n-heptane (54 g/l), polyethylene glycol (56 g/l), xylene (190 g/l). The tests on flammability, explosive or oxidising properties gave negative results. No selfignition at temperatures up to melting point (93 °C)

Particle size distribution was characterized by two methods: In laser diffractometric analysis of technical substance the proportion of particles under 50 µm was in the range of 2% - 8%. In a continuous drop method, the mass-% under the cut-off diameter of 4µm ("alveolar") was 0.008%, under 10 µm ("thoracic") 0.032%. The third fraction ("inhalable"), which is the sum of the two fractions and of the fraction on the 3rd filter, was 0.63 mass-% (rel.std dev. 22 %), for which the upper limit or particle size characteristics were not determined. The study did not characterise the proportion under the particle size diameter of 50 µm.

Physical and chemical properties of tolylfluanid are as in Product type 8, in its Document II A and in the Assessment Report. For properties of the metabolites, see the List of Endpoints.

Methods of Analysis

Analytical methods for the determination of tolylfluanid and its degradation product DMST in soil, air and water are given in Doc IIA. There are no other impurities of toxicological or environmental concern in the technical grade material. For impurities in the active substance, see the updated Confidential Annex. The limits of quantification for tolylfluanid and DMST are 0.01 mg/kg in soil, 0.05 µg/L in water, and 0.01mg/m^3 in air. Limits of quantification for tolylfluanid in analytical methods are at sufficiently low level compared with Predicted-No-Effect-Concentrations in different environmental compartments (soil and surface water) and human health aspects (air and potable water).

The residue analysis method that was validated for synthetic seawater needs to be justified during the product authorisation phase taking into account the sample matrix and appropriate limit of quantitation (LOQ). The presented LOQ is too high for evaluation of concentrations at PNEC. In synthethic seawater the limits of quantification for tolylfluanid and DMST were 1.02 µg/l and 0.98 µg/l. Valid data concerning validation of the analytical method for determination of residues in seawater need to be presented during the product authorisation stage with a LOQ at the level of the PNEC for both tolylfluanid and DMST.

Methods for residue analysis in animal and human body fluids and tissues were agreed to be submitted on tolylfluanid, as the small particle size fraction is classified as highly toxic. It was agreed at TM II2013 that a blood method evaluated for tolylfluanid in the ppp framework can be accepted for biocides as well. However, in bilater consultations thereafter, it was observed that the method needs further validation 6 months prior to product authorisation, as the validation of the methodology had some deficiencies when compared with the current requirements for analytical method validation.

No fully validated analytical methods for sediment, fish and shellfish are available. In bilateral discussions after TMII 2013, submitted methods for determination of tolylfluanid in matrices of animal origin (meat, milk, fat, eggs) were agreed applicable for determination of tolylfluanid in fish and shellfish. However, additional method validation 6 months prior to product authorisation shall be submitted. Tolylfluanid degrades rapidly in water and is not expected to concentrate in wild-caught fish or shellfish following the uses supported in the evaluation. The degradation products are soluble, as well. For the major degration product, DMST, the RMS has accepted a justification of non-submission of an analytical method. DMST is not expected to be concentrated in fish or shellfish. If antifouling products were applied for fish farming use, a new waiver or a method should be submitted for method of determination of DMST.

The Rapporteur is of opinion that an analytical method for detection of tolylfluanid in sediment is not needed. Tolylfluanid is not detected in sediment in water sediment studies and no sediment risk assessment was carried out for tolylfluanid, as agreed at TMIII 2011. Tolylfluanid degrades rapidly in water and does not concentrate in any water organisms. Analytical methods in sediment for the degradation products i.e. DMST and N,N-DMS, are not needed based on the fact that their water solubility is high and the log K_{OW} is low. Their possible presence in the environment can be measured in the water phase.

The analytical method for detection and identification of the metabolite N,N-dimethylsulfamide in water is acceptable.

2.1.2. Intended Uses and Efficacy

Tolylfluanid is intended to be used in antifouling products to protect the underwater hull of pleasure craft and commercial ships. In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

Panels treated with AF formulations containing 3% tolylfluanid and exposed to natural seawater at the TNO raft in the harbour of Den Helder at different depths showed effectiveness against green algae. No fouling at all were detected when panels were treated with AF formulations containing both 3% tolylfluanid and 20% copper oxide. Interspeed Ultra (containing 44.35 %w/w Cu2O and 2.76 % w/w tolylfluanid) a hard durable yacht antifouling paint designed for use on high-speed craft or craft on dry moorings showed effectiveness against various fouling organisms in static panel immersion test in the UK (Newton Ferrers and Burnham-on-Crouch) demonstrated that the product remained effective at deterring a range of fouling organisms up to a period of 12 months.

For products authorisation phase detailed and documented efficacy tests should be carried out.

There have not been any recorded cases of resistance in populations of fouling organisms through the use of anti-fouling paints. Such effects are unlikely to be observed due to the broad spectrum of algal and animal species controlled by these products and the general nature of the mode of action of active substances.

2.1.3. Classification and Labelling

The current classifications, below, are also the classifications proposed by the eMS. As agreed in the Commission's Technical Committee on Classification and Labelling of Dangerous Substances in March 2005 and included in the 31st ATP, the classification/labelling as in directive 67/548/EEC is given in Table 1 and Table 2. If tolylfluanid is not respirable to a toxicologically significant amount (containing < 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm, Index No.613-116-01-4), the classification shall be the following (see Table 1):

Table 1. Classification of tolylfluanid as in Directive 67/548/EEC,

Classification	
Index No Tolylfluanid containing < 0.1% (w/w) of particles with an aerodynamic diameter of below 50µm	613-116-01-4
Class of danger	Xi: Irritant; N: Dangerous for the environment
R-phrases	R 36/37/38: Irritating to eyes, respiratory system and skin R 43: May cause sensitisation by skin contact; R 50: Very toxic to aquatic organisms Specific concentration limits (for environmental classification): N; R50: C ≥ 2.5%
S-phrases	(S 2): Keep out of the reach of children; S 25: Avoid contact with eyes; S 36/37: Wear suitable protective clothing and gloves; S 46: If swallowed, seek medical advice immediately and show this container or label S 61: Avoid release to the environment. Refer to special instructions/Safety data sheets

If the substance is respirable to a toxicologically relevant amount (containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm, Index No. 613-116-00-7), the classification shall be the following (see Table 2):

Table 2. Classification of tolylfluanid as in Directive 67/548/EEC**,**

Classification	
Index No. Tolylfluanid containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50µm	613-116-00-7

Class of danger	T+: Very toxic N: Dangerous for the environment
R-phrases	R 26: Very toxic by inhalation; R 48/23: Toxic: danger of serious damage to health by prolonged exposure through inhalation; R 36/37/38: Irritating to eyes, respiratory system and skin; R 43: May cause sensitisation by skin contact; R 50: Very toxic to aquatic organisms Specific concentration limits (for environmental classification): N; R50: C ≥ 2.5%
S-phrases	(S 1/2): Keep locked up and out of the reach of children; S 28: After contact with skin, wash immediately with plenty of (to be specified by the manufacturer); S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection; S 45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible); S 61:Avoid release to the environment. Refer to special instructions/Safety data sheets; S 63: In case of accident by inhalation: remove casualty to fresh air and keep at rest Alternatively: S(1/2)-28-36/37/39-45-63-61

The classification in accordance with criteria in Regulation (EC) No 1272/2008, for tolylfluanid (Index No 613-116-01-4) containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm, is in Table 3. The RMS is not proposing any changes in classification.

Table 3. Classification in accordance Regulation (EC) No 1272/2008

Index No Tolylfluanid containing < 0.1% (w/w) of particles with an aerodynamic diameter of below 50µm	No 613-116-01-4
Hazard Class and Category Code(s)	Eye Irrit. 2 STOT SE Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Cronic 2[§]
Hazard Statement Code(s)	H319 H335 H315 H317 H400 H411
Supplemental Hazard Statement Code(s)	H410:very toxic to aquatic life with long lasting effects.

Pictogram(s) and Code(s)	GHS07	GHS09	Wng
Signal Word (Code)	Warning (Wng)		
Specific Concentration Limits. M-Factors	M=10 (Aquatic acute 1)		
Notes §Aquatic chronic 2 classification is proposed according to 286/2011.	-		

The classification in accordance with criteria in Regulation (EC) No 1272/2008, for tolylfluanid (Index No 613-116-00-7) containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm, is in Table 4. The RMS is not proposing any changes in classification.

Table 4. Classification in accordance with Regulation (EC) No 1272/2008

Index No Tolylfluanid containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50µm	No 613-116-00-7		
Hazard Class and Category Code(s)	Acute Tox. 2* STOT RE 1 Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Cronic 2§		
Hazard Statement Code(s)	H330 H372** H319 H335 H315 H317 H400 H411		
Supplemental Hazard Statement Code(s)	H410:very toxic to aquatic life with long lasting effects.		
Pictogram(s) and Code(s)	GHS06	GHS08	GHS09
Signal Word (Code)	Danger (Dgr)		
Specific Concentration Limits **M Factors**	M=10 (Aquatic acute 1)		
Notes §Aquatic chronic 2 classification is proposed	-		

according to 286/2011.	

Under the CLP Regulation the classification of tolylfluanid as a skin sensitizer needs to be distinguished between category 1A and 1B. This was not required under the previous dangerous substances legislation. The substance is currently classified sensitizer R43.

Classification of the Representative Product

Based on testing of the representative product,the product should not be classified as harmful via the oral, dermal or inhalation route. The product should be classified under Directive 67/548/EEC as Harmful (Xn) and Dangerous for the environment (N) and the following Risk phrases should be used: R10, R41, and R50-53. A Bühler-Test run with Interspeed Ultra did not reveal sensitising effects of this product. However, tolylfluanid may cause sensitisation by skin contact and it is classified as a sensitizer. The concentration of tolylfluanid in the product is higher than 1 % w/w. According to Directive 1999/45/EC, a standard phrase should be added: "Contains <name of sensitizing substance(s)>. May produce an allergic reaction".

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Health effects of the active substance, tolylfluanid, have been addressed in detail in Document IIA. The studies have been evaluated earlier under PT 8 (wood preservatives). The following text on hazard identification of tolylfluanid has been taken from the AR of tolylfluanid for PT 8, with minor clarifications and rearrangements in structure of the text.

Tolylfluanid is extensively and rapidly absorbed by the oral route. Oral and dermal toxicity is low. Tolylfluanid (dusty forms) possesses low to high acute inhalation toxicity, depending on particle size, leading to a differentiated proposal for classification. Toxicity through inhalation of a liquid aerosol is low. LOAEL/LOAEC and NOAEL/NOAEC values from key studies are summarised in Table 5.

Tolylfluanid may cause sensitisation by skin contact, and it has irritating properties on both skin and eyes. Studies on acute inhalation toxicity indicate strong irritation of the whole respiratory system leading to deaths.

Depending on particle size, tolylfluanid containing ≥ 0.1% particles < 50µm is toxic by prolonged exposure through inhalation. Effects during short term oral exposure included functional disturbance of the thyroid, increased liver weights and decreased liver enzyme levels in the rat and the dog, and slight histo-pathological changes in the kidney in the dog at high dose levels.

Tolylfluanid is not proposed to be classified as mutagenic, based on the overall in vivo data pointing towards negative results, although some positive or equivocal genotoxicity test results were encountered in the sole acceptable in vitro chromosome aberration test and in some of the tests for gene mutations in mammalian cells. Tolylfluanid is not carcinogenic.

No evidence of neurotoxicity was observed. As agreed in TM II 2013 SE has sent a statement on assessment of genotoxicity (January 2014): "SE considers the overall conclusion that the clastogenic effects observed *in vitro* cannot be expressed *in vivo* (i.e. tolylfluanid should not be considered as mutagenic *in vivo*) to be based on weak data." See also Doc IIA and the revised Doc IIIA6.6.4.

Health Hazards of the Representative Product

For classification of the representative product, see 2.1.3., above. For health hazards, see Doc IIB.

Antifouling paints are complex mixtures of ingredients designed to aid the application of the antifouling paint. These mixtures include solvents fillers, pigments and plasticiser which alter the physical properties of the paint in order to achieve acceptable finishes of the paint on the vessel. It is anticipated that the PPE recommended for use of these products will provide sufficient protection of the worker on professional applications.

2.2.1.2. Effects assessment

Table 5. Relevant LOAEL/LOAEC and NOAEL/NOAEC settings

Study	End point	LOAEL/LOAEC	NOAEL/LOAEC
18-day dermal, rabbit	Systemic effects Dermal local effects	>300 mg/kg/day ≤ 1 mg/kg/day	300 mg/kg/day (highest dose tested) <1 mg/kg/day
13-week oral, dog	Increased liver and thyroid weights	93-99 mg/kg/day	33 mg/kg/day
4-week inhalation, rat	Irritation in larynx and lungs (histopathology) Moderate to marked squamous epithelial metaplasia.	4 mg/m³	1 mg/m³
One-year oral, dog	Effects on liver, kidney and body weight	62.5-125 mg/kg/day	12.5 mg/kg/day
Two-year oral, rat	Bone and teeth alterations (Effects on liver, kidney and thyroid at higher dose levels)	90 mg/kg/day	18 mg/kg/day
Teratogenicity, rats	Maternal toxicity Developmental effects	100 mg/kg/day >1000 mg/kg/day	<100 mg/kg/day ≥ 1000 mg/kg/day
Teratogenicity, rabbits	Maternal toxicity, Postimplantation loss, increased incidence of malformations, placental alterations	≤ 70 mg/kg/day	25 mg/kg/day
Two-generation, rat	Decreased parental weight gain Reduced body weight and spleen weight in F1 animals (pups)	237 mg/kg/day 54.1 mg/kg/day	46.8 mg/kg/day 14 - 31.5 mg/kg/day
Acute neurotoxicity, oral, rat	Neurotoxicity	> 2000 mg/kg	≥ 2000 mg/kg
13-week neurotoxicity, oral, rat	Neurotoxicity General toxicity	> 620 mg/kg/day 620 mg/kg/day	≥ 620 mg/kg/day 109 mg/kg/day

Critical endpoints: The critical effects of tolylfluanid are the histopathological changes in bone and teeth, caused by fluoride, at a level of 90 mg/kg bw/day. **A chronic NOAEL of 18 mg/kg bw/day** was deduced from a **2-year rat oral study**. At higher dose levels

also increased liver and kidney weights, slightly increased thyroid follicular cell hyperplasia and adenomas were observed.

In a **rabbit teratogenicity study** increased postimplantation loss, increased incidence of malformations and placental alterations, and maternal toxicity (slight impairment of body weight development) were observed. However, the developmental effects and maternal toxicity were marginal, and criteria for classification were not met. From the study **a NOAEL of 25 mg/kg bw/day** was derived.

In Table 5 there are studies with lower NOAELs than those selected for deriving the AELs, see below. The reasons for not choosing studies with lower NOAELs, the two-generation (rat) study or the one-year dog study are the marginality of effects or study not being a guideline study, respectively. However, the two-generation study had been chosen for a basis of the ADI in the ppp framework.

Setting of Acceptable Exposure Levels (AEL)

The most relevant studies for setting the AEL values were considered to be the 2-year oral study in rat for the long term exposure and the teratogenic study in rabbit for the short term exposure. The medium-term AEL is identical to the long-term AEL, but it is not used in the risk characterization. The safety factor of 100 was used in deriving the reference values. The reference values and the relevant NOAEL-values are summarised in Table 6. The reference values are applicable both to primary exposure in professional and non-professional use, as well as to secondary exposure.

Table 6. Acceptable Exposure Levels (AEL) for risk assessment

Study	**NOAEL** **mg/kg bw/day**	**AEL** **mg/kg bw/day**	**Exposure**	**Relevance for risk assessment**
2-year oral study, rat	18	0.18 long-term AEL	Professional workers	long-term exposure (most days per year, or repeated exposure)
2-year oral study, rat	18	0.18 medium-term AEL - **not used in this assessment**	Professional workers	repeated exposure (few weeks per year or frequent exposure)
teratogenicity study, rabbit	25	0.25 short-term AEL	Non-professionals	Short term/acute exposure (a single dose or a few days of exposure)

The ADI and ARfD were agreed to be included in the TM II 2013. However, the values are not used for risk characterization in this product type.

ADI: Acceptable Daily Intake (ADI) is based on the same value as already established for PPP regulatory framework. Thus ADI is 0.1 mg/kg bw/day.

ARfD: Acute Reference Dose (ARfD) is based on the same value as already established for PPP regulatory framework, related to the teratogenicity study (rabbit). The ARfD is 0.25 mg/kg bw/day.

2.2.1.3. Exposure assessment

Both primary and secondary exposure to tolylfluanid in humans was estimated. Calculations were performed according to the recommendations of the TNsG – Human Exposure to Biocidal Product (2002) and the User Guidance (2002) with HEEG amendments.

In all cases a tiered approach was used. The Tier 2 assessments more accurately represent the likely usage scenarios that occur for antifouling paint application in professional use. For non-professional brushing and rolling the risk assessment is acceptably passed already at Tier 1, assuming no clothing and no gloves. The detailed calculations are presented in document IIB. The bodyweight value was 60 kg for an adult. In the primary exposure scenarios, a dermal delivery rate of 3.3 % was used, which was determined from the example product Interspeed Ultra (2.76 % a.s. w/w). The primary exposure scenarios considered in the human risk assessment are:

- professional mixing and loading (potman) (Mixing and Loading Model 6)
- professional airless spraying (sprayer, covering also ancillary workers) (Spraying Model 3)
- professional brushing and rolling (Consumer Product Painting Model 4, revised by HEEG)
- non-professional brushing and rolling (Consumer Product Painting Model 4, revised by HEEG)
- professional paint removal (HEEG OPINION on the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints)
- non-professional paint removal (HEEG OPINION on the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints)

Primary exposure

Professional exposure

Primary exposure scenarios for professionals included operators in specialized applications (sprayers, potmen) and other professionals (painting by brushing or roller), and paint removal (Table 7 and Table 8).

Dermal and inhalation exposure to the other components of the product have been also taken into account (see Document IIB). The exposure to the products can be reduced to acceptable levels by using personal effective protective measures.

Table 7. Summary of exposure in professional applications

Intended use (product type)	**Exposure scenario**	**PPE**	**Inhalational uptake** mg/person/day	**Dermal uptake** mg/person/day	**Systemic Dose** mg/kg bw/day
21 (Antifouling products) Product: 2.76% tolylfluanid	Airless spraying viscous solvent-based liquids at > 100bar pressure, overhead and forwards (sprayers, covering also ancillary workers).	Tier 1: no PPE	1.79	60.5	1.04
		Tier 2a: gloves, impermeable coverall (5 % penetr.), RPE (APF 10)	0.179	2.38	0.043
		Tier 2b: gloves, double coverall (1 % penetr.), RPE (APF 40)	0.045	0.744	0.013
	Loading liquid antifoulant into reservoir for airless spray application. (potmen)	Tier 1: no PPE	0.2	20.0	0.34
		Tier 2a: gloves, single impermeable coverall (5 % penetr.), no RPE	0.20	2.1	0.038
		Tier 2b: gloves, single impermeable coverall (5 % penetr.), RPE (APF 10)	0.020	2.1	0.035
	Cleaning of spray equipment	Tier 2: gloves, single impermeable coverall (5 % penetr.)	-	0.0334	0.00056

	Brush and roller application of antifoulant (135 min)	Tier 1: no PPE	0.0039	13.2	0.22
	Brush and roller application of antifoulant (90 min)	Tier 2a: gloves, 100 % clothing penetration, no RPE	0.0026	4.03	0.067
		Tier 2b: gloves, single impermeable coverall (5 % penetr.), RPE (APF 10)	0.00026	1.64	0.027
	Brush and roller application of antifoulant (90 min) + cleaning of a brush	Tier 2a: gloves, 100 % clothing penetr.), no RPE	0.0026	4.05	0.068

Table 8. Summary of professional exposure levels to antifouling removal

Intended use (MG/PT)	**Exposure scenario**	**PPE**	**Inhalational uptake** mg/person/day	**Dermal uptake** mg/person/day	**Systemic Dose** mg/kg bw/day
Professional: PT21 2.76% Tolylfluanid	Paint removal using hydroblasting or grit blasting (180 min) (covering also grit fillers)	Tier 1: No	1.81	7.38	0.153

Professional: PT21 2.76% Tolylfluanid	Paint removal using hydroblasting or grit blasting (180 min) (covering also grit fillers)	Tier 2: Protective clothing and RPE (40)	0.045	0.91	0.016

Non-professional exposure

Application by brush and roller (Table 9) as well as in some cases paint removal are the only applications envisaged for non-professional users.
Assuming a clothing penetration value of 100 %, acceptable risks were indicated for a formulation containing 2.76 % tolylfluanid.

Table 9. Summary of non-professional exposure levels to antifouling brush and roller application including cleaning of a brush and in antifouling removal.

Intended use (product type)	**Exposure scenario**	**PPE**	**Inhalational uptake mg/person/day**	**Dermal uptake mg/person/day**	**Systemic dose mg/kg/day**
21 Antifouling products; Product: 2.76% tolylfluanid	Brush and roller application	Tier 1: No (100% penetration)	0.0026	8.84	0.147
	Brush and roller application + cleaning of a brush	Tier 1: No (100% penetration)	0.0026	8.99	0.150
Non-professional*: PT21 2.76% Tolylfluanid	Paint removal using hydroblasting or grit blasting (90 min)	Tier 1: No (100% penetration)	0.9	3.69	0.077

Secondary exposure

Cleaning of working clothes at home:
It is proposed that people can be at risk when using a washing machine to launder contaminated coveralls at home. The worst-case exposure is via the dermal route – mainly to the hands - from handling the contaminated clothing prior to introduction into the washing machine. This is considered to be a short-term exposure scenario (e.g. <24 hours).

It is unlikely that professional workers involved in airless spraying of ship's hulls would take coveralls home to be washed. Exposure of laundry workers has not been considered here; exposure in a laundry in cleaning of working clothes of professional workers is considered to be lower than the acceptable exposure of professionals in primary exposure. People more likely to be at risk are non-professionals who handle contaminated clothing following application of antifoulants by chandlers and non-professionals. As the worst case, the duration of application by brush/roller is 135 minutes/day (time of contamination of a coverall) (Table 10).

Child touching a boat surface:
A scenario of a child touching a wet boat surface was added and the risk was found acceptable. Two ways for calculation were presented, the exposure values were 0,15 and 0,22 mg/kg/day, respectively.

Table 10. Summary of secondary exposure

Exposure Scenario (indicated duration)	**Estimated Internal Exposure (mg/kg bw)**			
	estimated oral uptake	**estimated inhalation uptake**	**estimated dermal uptake**	**estimated total uptake**
Cleaning work clothes at home (Short-term)				
Worst case (application = 135 min/day)	NA	NA	0.0014	0.0014
Refined case (application = 90 min/day)	NA	NA	0.00093	0.00093
Child touching a boat surface (Acute)				
A)	NA	NA	0.15	0.15
B)			0.22	0.22

Exposure to substances of concern (SOC)

In Document II B Section 3.2.6 exposure to substances of concern in the product is briefly assessed in professional use.

2.2.1.4. Risk characterisation

Professional users – primary exposure

Application:

Primary exposure scenarios for professionals included operators in specialized applications (sprayers, potmen) and other professionals (painting by brushing or roller), and paint removal.

Table 11. Summary of risk characterisation for primary exposure, application, professional users

Scenario	**Exposure path**	**PPE**	**Systemic body dose mg a.s./kg bw/day**	**MOE***	**Exposure/AEL***
Airless spraying viscous solvent-based liquids at > 100 bar pressure, overhead and forwards (sprayers, covering also ancillary workers)	Dermal and inhalation	Tier 1: no PPE	1.04	17	5.8
		Tier 2a: gloves, impermeable coverall (5 % penetr.), RPE (APF 10), eye/face protection	0.043	420	0.24
		Tier 2b: gloves, double coverall (1 % penetr.), RPE (APF 40), eye/face protection	0.013	1385	0.07
Loading liquid antifouling paint into reservoir for airless spray application. (potmen)	Dermal and inhalation	Tier 1: no PPE	0.34	53	1.9
		Tier 2a: gloves, single impermeable coverall (5 % penetr.), no RPE	0.038	474	0.21
		Tier 2b: gloves, single impermeable coverall (5 % penetr.), RPE (APF 10), eye/face protection	0.035	514	0.19
Cleaning of spray equipment	Dermal	Tier 2: gloves, single impermeable coverall (5 % penetr.)	0.00056	32000	0.003

Brush and roller application of antifouling paint (cleaning of a brush added)	Dermal and inhalation	Tier 1: no PPE (time 135 min)	0.22	82	1.2
		Tier 2a: gloves, 100% clothing penetration, no RPE, eye/face protection (time 90 min)	0.068	265	0.38

* NOAEL = 18 mg/kg bw/day, $AEL_{long\ term\ (medium\text{-}term)}$ = 0.18 mg/kg bw/day

Risks in professional applications are acceptable in Tier 2 (Table 11). The lowest MOE was 265 for the professional painter; Brush and roller application, including cleaning of a brush.

Professional sprayers must wear full face mask with tear off vision strips (air-fed or equipped with solvent and particulate filters, protection factor 10), single impermeable coverall and gloves. Other professionals (potman) must wear single impermeable coverall, gloves and eye protection. Professionals in brush and roller application must wear gloves and eye protection.

Dermal and inhalation exposure to the other components of the products have been also taken into account. The risk assessment indicated that the risk is acceptable for operators involved in antifouling applications, if protective clothing and, in working phases with inhalation exposure, RPE are used.

Cleaning of spray equipment scenario was added for information only, following discussions at the Biocides Technical Meeting. Further agreement and descriptive information from the antifouling industry on this scenario, submitted in May 2014 to the eCA, was not included as it had not yet been discussed at the ad hoc Working group on Human Exposure. Should this ad hoc Working Group consider it an appropriate scenario for all antifouling products with spray applications, the scenario might be included in the risk assessment at product authorisation stage.

Paint removal:

In paint removal the risks were acceptable when RPE, gloves and coverall were used (Table 12).

Table 12 Paint Removal using Hydroblasting or Grit Blasting**.**

Scenario	**Exposure path**	**PPE**	**Systemic body dose mg a.s./kg bw/day**	**MOE***	**Exposure/AEL ***
Professional*: Paint removal using	Dermal and inhalation	Tier 1: No	0.153	117	0.85
		Tier 2: RPE,	0.016	1125	0.09

hydroblasting or grit blasting a product containing initially 2.76 % tolylfluanid (180 min) (covering also grit fillers)		gloves, coverall			

* NOAEL = 18 mg/kg bw/day, $AEL_{long\text{-}term}$ = 0.18 mg/kg bw/day for professionals

For professionals using hydroblasting or gritblasting the MOE was 1125 when PPE was used. In paint removing professional operators must wear full face mask with tear off vision strips (air-fed or equipped with solvent and particulate filters, protection factor 40), impermeable coverall (penetration 5%) and gloves.

Non-professional users – primary exposure

Application by brushing (roller) as well as in some cases paint removal are the only applications envisaged for non-professional users (Table 13).

Table 13. Summary of risk characterisation for primary exposure, non-professional painters

Scenario	**Exposure path**	**PPE**	**Systemic body dose mg a.s./kg bw/day**	**MOE***	**Exposure/AEL***
Non-professional Brush and roller application of an antifouling paint containing 2.76 % tolylfluanid (cleaning of a brush added)	Dermal and inhalation	Tier 1: No (100% clothing penetration)	0.150	167	0.6
Non-professional: Paint removal using hydroblasting or grit blasting a product containing initially 2.76 % tolylfluanid (90 min)	Dermal and inhalation	Tier 1: No (100% clothing penetration)	0.077	324	0.31

* = NOAEL= 25 mg/kg bw/day, $AEL_{short\text{-}term}$ = 0.25 mg/kg bw/day

Assuming a clothing penetration value of 100 %, acceptable risks were indicated for formulation containing 2.76 % tolylfluanid. The lowest MOE was 167.

Paint removal, non-professionals:

In paint removal 100% clothing penetration was assumed to be used. The MOE of 324 (see Table 13) is considered as a very conservative value, since the non-professionals normally use less efficient methods for removing paint, in comparison to professional operators. Wire brushing and sand paper are usually used by non-professionals to remove the top layers of paint only.

Secondary exposure

For professional applications co-workers of operators, wearing coveralls and gloves, could be exposed to some extent to the product. Such exposure however will be considerably lower than that of the actual operator, and it is not foreseeable as chronic exposure.

For non-professionals, scenarios of Cleaning of working clothes at home have been added (Table 14). For both the worst case and the refined case, the MOEs are 18 000 and 27 000, respectively.

Exposure of laundry workers was not considered, since exposure in a laundry in cleaning of working clothes of professional workers is expected to be lower than the exposure of professionals in primary exposure, which was at acceptable level. Sensitisation of laundry workers was not assessed.

A scenario of a child touching a wet boat surface was also added and the risk was found acceptable. Two ways for calculation were presented, the MOEs were 166 and 114, respectively.

Table 14. Summary of Secondary Exposure

Scenario	**Systemic body dose mg a.s./kg bw/day**	**MOE***	**Exposure/AEL***
Cleaning of working clothes (Short-term)			
Worst case (application of antifouling = 135 min/day)	0.0014	18000	0.006
Refined case (application of antifouling = 90 min/day)	0.00093	27000	0.004
Child touching a boat surface (Acute)			
A)	0.15	166	0.6
B)	0.22	114	0.88

* NOAEL = 25 mg/kg bw/day, $AEL_{short\text{-}term}$ = 0.25 mg/kg bw/day for non-professionals

Combined exposure

There is no combined exposure foreseen with systemic doses from two tasks or exposure scenarios. Cleaning of a brush is already added in the scenarios of Brush and roller application of an antifouling product.

Fluorine from tolylfluanid

In analogy to PT 8 assessment, the amount of fluorine derived from the highest systemic dose in professional work was calculated. For the scenario for professional painter (brush and roller application, time 135 min) with PPE, the scenario with the highest systemic tolylfluanid dose (0.041 mg/kg bw/day), the daily amount of fluoride (0.14 mg) was calculated. Hence, fluoride from tolylfluanid used in antifouling product does not pose a risk to humans.

Substances of concern and product specific properties

Exposure in professional use to concentrations of solvents were compared to their occupational exposure level (OEL) values as given in directive 2000/39/EC and were estimated lower. Concentrations of vapours exceeding occupational exposure limits in areas of application and storage should be prevented by good ventilation. One of the solvents with a concentration of ca 10 % w/w has to be classified as Carc. Cat. 2; R45 if the content of benzene is ≥ 0.1 %. Hence, the content of benzene in the solvent has to be lower than 0.1 % in the tolylfluanid product. Health effects of the solvents and other substances of concern (SOC) in the representative biocidal product have been addressed in Document IIB (Ch 4).

Since many of the risks in the use of the representative product may be related to substances other than tolylfluanid in the product, the product properties and risk mitigation measures should be presented and assessed in product authorisation stage.

Conclusion - tolylfluanid

The antifouling use of tolylfluanid, in biocidal product Interspeed Ultra, can be considered safe for professional users with effective protective clothing and RPE.

Also for non-professionals the systemic exposure to tolylfluanid was at acceptable level. Tolylfluanid is a sensitizing substance, but the sensitizing potential in products may vary depending on the other constituents of the mixture. Therefore the product properties and appropriate risk mitigation measures should be assessed in product authorisation stage.

Risk characterization of the metabolite N,N-dimethylsulfamide (N,N-DMS) and NDMA

Tolylfluanid and its metabolite DMST were found to yield N-nitrosodimethylamine (NDMA), in ozonation of water via a novel degradation product identified during plant protection product assessment, N,N-dimethylsulfamide. Risk was assessed later also for product type 8 (Wood Preservative) uses under the Biocides Directive. The maximum transformation efficiency of 32% (in units of µg or µg/l) can be used in calculating of NDMA formation in ozonation. The information on properties of N,N-dimethylsulfamide did not suggest that this substance is hazardous to health. However, the hazard assessment was based on a limited set of studies. The limited toxicological information on N,N-dimethylsulfamide does not suggest an unacceptable risk at a level below 0.1 µg/l. The opinion of TM I 2008 was that the substance is not a genotoxic substance. In a 28 day oral repeated dose (subchronic) study in rat, mineralisation of kidneys in females in the high dose level was the only effect found, but no NOAEL could be set with certainty. However, the TM I 2008 proposed to include, for information, also an (alternative) NOAEL of 200 mg/kg bw/day.

NDMA however is genotoxic, mutagenic and carcinogenic (Carc. Cat. 2). NDMA has been classified by IARC in Group 2A "probably carcinogenic to humans" (IARC, 1987). The risk assessment of N,N-dimethylsulfamide and of NDMA by the RMS was included in a separate Risk Assessment report, as a supplementary part to tolylfluanid risk assessment in PT 8. This assessment included information from the applicant, and also information on NDMA which is based on information in WHO publications. Since then, the RMS has not received any new toxicological hazard information on these substances. It was agreed in the TMI08 that drinking water limit value of 0.1 µg/l shall be used in the risk assessment. Toxicological information on N,N-dimethylsulfamide, submitted as a Supplement in the AR for PT 8, has now been included in the Document II A.

For risk characterization, concentrations of N,N-dimethylsulfamide or NDMA, derived from tolylfluanid or from a related substance, dichlofluanid, can be used. In the environmental risk assessment (2.2.2.) concentrations of N,N-dimethylsulfamide in monitoring studies, modelling studies or in freshwater calculations exceeded the limit of 0.1 µg/l, as a result of use of tolylfluanid or a similar substance, dichlofluanid, as an antifouling paint in fresh-water. Hence, unacceptable risk for human health cannot be excluded from freshwater uses. Antifouling paints with tolylfluanid in the Application are intended for vessels, super-yachts or pleasure crafts used in sea-water, only. **Safe use for tolylfluanid in antifouling products, considering the potential for NDMA formation via a degradation product, N,N-DMS, is limited to marine waters.**

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

For the calculation of the PECs of tolylfluanid, the degradation in the environmental compartments of concern was taken into account. Therefore, where appropriate, the PECs were calculated also for the major metabolites (formed ≥10%) of tolylfluanid, i.e. DMST (dimethylsulfotoluidid), DMST-acid and N,N-DMS (N,N-dimethylsulfamide). Degradation pathway of tolylfluanid in soil and in water is likely the same; tolylfluanid is degraded to DMST, DMST- acid and finally N,N-DMS.

Tolylfluanid hydrolyses rapidly rapidly in neutral and alkaline conditions, i.e. DT50 was 40 hours at pH 7 (20 °C) in freshwater and 4.3 hours at pH 8 (20 °C) in seawater.. DMST was the only major degradation product formed in hydrolysis. DMST and N,N-DMS were hydrolytically stable.

In water/sediment study tolylfluanid dissipated within one day from water and was never detected in sediment phase. The whole system degradation half-life was 0.3 day 20 °C (0.6 days at 12°C). DMST and N,N-DMS were detected >10% both in the water and in the sediment phase. DMST- acid was detected only at one sampling point >10% and in the water. The whole system DT50 of DMST, DMST- acid and N,N-DMS was 48 days at 20 °C (91 days at 12°C), 10 days at 20°C (19 days at 12°C) and >1000 days at 20 °C (>1896 days at 12°C), respectively.

Tolylfluanid degrades rapidly in soil and the major degradation products were DMST and N,N-DMS. DT50 of Tolylfluanid was 0.8 days at 20 °C (1.5 days at 12°C). DT50 of DMST and N,N-DMS were 2.9 days at 20 °C (5.5.days at 12°C) and 699 days at 20 °C (1325 days at 12°C), respectively.

Due to the low vapour pressure of tolylfluanid (2.5 x10-4 Pa) it is unlikely that it evaporates in significant quantities. According to Henry's law constant (7.7 x 10-2 Pa.m-

3.mol-1) tolylfluanid will have a slight tendency to volatilise from aqueous solutions. The photochemical half-life of tolylfluanid in air was calculated to be 21.5 hours and the respective chemical lifetime 1.3 days. Based on the log Kow of 3.9 and log Koc of 3.35 tolylfluanid has a potential to bind to suspended solids and sediment, but that was not detected in the water/sediment study.

In order to address a potentially severe underestimation of the risk to sediment dwelling organisms from exposure via suspended matter, caused by the fact that sorption data (Koc) has only been studied at concentrations which are not fully relevant in the marine environment, a new study on sorption at environmentally relevant conditions (concentrations µg/l to ng/l, pH ~8, DOC not too high, etc.) is to be performed before the antifouling active substances are evaluated for a potential renewal of the approval.

This new sorption study should ideally be carried out in the same laboratory for all antifouling substances which are on the market at the time. By using the same seawater and sediment, the study will provide harmonized sorption data of relevance to marine environmental conditions. The study should as a minimum follow the OECD guidelines, unless by then, established scientific progress in the field of sediment risk assessment indicates other directions (SETAC books, OECD guidelines). Since low concentrations are to be studied, technical problems with limits of quantification may need to be addressed as stated in OECD 106 §34 by selecting appropriate amounts of sample matrix (water and sediment), possibly this will mean up-scaling of the traditionally small amounts used, or new test methods. An outline test protocol will by then have to be developed and agreed by the e-consultation group (of TM 2012) in dialogue with sorption researchers.

DMST has good photostability and its photochemical oxidative degradation half-life in air is 0.3 days (7 hours) (24-hr day; 0.5E6OH/cm3) and the respective chemical lifetime 0.4 days. Photodegradation of N,N-DMS has not been studied or estimated. Both metabolites have low vapour pressure and Henry's law constant and they are not expected to distribute in air in significant quantities. DMST and N,N-DMS are not expected to bind significantly in suspended solids, sediment or soil. Log Kow of DMST and N,N-DMS are 1.99 and -0.8, respectively. Log Koc of 1.76 and 1.97 were determined for DMST in marine and freshwater sediment, respectively. N,N-DMS showed no adsorption in the adsorption study (OECD 106) and hence it was not possible to determine log Koc.

Based on the BCF value of 74 l/kg tolylfluanid and its residues are slightly accumulating in fish. The depuration rate is quite fast. DMST and N,N-DMS do not seem to have potential for bioconcentration due to their hydrophilic properties and low Kow values (DMST: solubility 677 mg/l and log kow 1.99, N,N-DMS: solubility 140 g/l and log kow -0.8 at pH 7 at 20°C).

2.2.2.2. Effects assessment

2.2.2.2.1. PNEC in water

According to the TGD fresh water and salt water data can be pooled for effect assessment and PNEC derivation if the difference in sensitivity between fresh water and marine species within trophic levels is not larger than a factor of 10. No systematic difference between freshwater and marine organisms was detected for tolylfluanid and DMST and hence pooled data have been used for the PNEC derivation.

Tolylfluanid

Acute
- Rainbow trout (*Oncorhynchus mykiss*): LC50 (96 h) = 0.016 mg/l
- Daphnid (*Daphnia magna*): LC50 (48 h) = 0.19 mg/l
- Algae (*Selenastrum capri-cornutum*): ErC50 (72 h) = 0.402 mg/l

Chronic
- Fathead Minnow (*Pimephales promelas*): NOEC (33 d) = 0.00407 mg/l (Dichlofluanid)
- Daphnid (*Daphnia magna*): NOEC (21 d) = 0.00265 mg/l (Dichlofluanid)
- Algae (*Selenastrum capri-cornutum*): NOEC (72 h) = 0.0402 mg/l

$PNEC_{fresh\ water}$ is 0.265µg/l. It is derived from the chronic invertebrate study conducted with dichlofluanid by using an AF of 10 according to the TGD (Part II), Table 16.
$PNEC_{sea\ water}$ is 0.0265 µg/l. It is derived from the chronic invertebrate study of dichlofluanid by using an AF of 100 according to the TGD (Part II), Table 25.

DMST

Acute
- Sheepshead minnow (*Cyprinodon variegatus*): LC50 (96 h) = 27.5 mg/l
- Mysid shrimp (*Mysidopsis bahia*): EC50 (48 h) = 21.5 mg/l (marine species)
- Algae (*Navicula pelliculosa*): ErC50 (72 h) = 46 mg/l

Chronic
- Fathead Minnow (*Pimephales promelas*) early-life-stage, NOEC (32 d) ≥ 10 mg /l
- Daphnid (*Daphnia magna*), NOEC (21 d) = 5.6 mg /l
- Midge (*Chironomus riparius*) EC5 = NOEC (28 d) = 1.4 mg/l
- Algae (*Navicula pelliculosa*) NOErC (72 h) = 12.3 mg /l

$PNEC_{fresh\ water}$ is 0.14 mg/l. It is derived from EC5 of 1.4 mg/l by using an AF of 10 according to the TGD (Part II), Table 16.

$PNEC_{sea\ water}$ is 0.014 mg/l. It is derived from EC5 of 1.4 mg/l by using an AF of 100 according to the TGD (Part II), Table 25.

PNEC of DMST is used for DMST-acid, because DMST-acid is considered less toxic to organisms than DMST based on the phys-chem properties, degradation status and QSAR predictions. No data are available for DMST-acid.

N,N-DMS

Acute
- Rainbow trout (*Oncorhynchus mykiss*) LC50 (96 h) >100 mg/l
- Daphnid (*Daphnia magna*): EC50 (48 h) > 100 mg/l
- Algae (*Pseudokirchinella subcapitata*): ErC50 (72 h) >100 mg/l

Chronic
- Rainbow trout (*Oncorhynchus mykiss*) NOEC (28 d) =100 mg /l
- Daphnid (Daphnia magna), NOEC (21 d) =100 mg /l
- Algae (*Pseudokirchinella subcapitata*): NOErC (72 h) =100 mg/l

$PNEC_{fresh\ water}$ is 10 mg/l. It is derived from 100 mg/l chronic study by using an AF of 10 according to the TGD (Part II), Table 16.

$PNEC_{sea\ water}$ is 1 mg/l. It is derived from 100 mg/l chronic study by using an AF of 100 according to the TGD (Part II), Table 25.

2.2.2.2.2. PNEC in sediment

Tolylfluanid

Sediment PNEC for tolylfluanid was not derived because sediment risk assessment was not carried out due to the very rapid degradation of tolylfluanid in the water. Besides, tolylfluanid was not detected in the sediment compartment in the fresh water/sediment test. At the TMII 2013 it was concluded that surface water risk assessment can be considered protective enough for the sediment dwellers.

DMST

Acute

- Benthic amphipoda (*Leprocheirus plumulosus*) LC50 (10 d) = 16 mg/kg ww

$PNEC_{sediment\ freshwater}$ is 0.016 mg/kg ww (0.074 mg/kg dw) based on an AF of 1000 according to the TGD (Part II), Chapter 3.5.4.

$PNEC_{sediment\ freshwater}$ is 0.341 mg/kg ww (1.57 mg/kg dw) based on the equilibrion partitioning method with $PNEC_{freshwater}$ of 0.14 mg/l according to the TGD (Part II), Chapter 3.5.4.

$PNEC_{sediment\ sea\ water}$ is 0.0016 mg/kg ww (0.0074 mg/kg dw) based on an AF of 10000 according to the TGD (Part II), Chapter 4.3.2.4.

$PNEC_{sediment\ sea\ water}$ is 0.0341 mg/kg ww (0.16 mg/kg dw) based on the equilibrium partitioning method with PNECaquatic of 0.014 mg/l according to the TGD (Part II), Chapter 4.3.2.4.

N,N-DMS

$PNEC_{sediment\ fresh\ water}$ and $PNEC_{sediment\ sea\ water}$ for N,N-DMS is 8 mg/kg ww (37 mg/kg dw) and 0.8 mg/kg ww (3.7 mg/kg dw), respectively. These are calculated based on equilibrium partitioning method with $PNEC_{freshwater\ r}$of 10 mg/l and $PNEC_{marine}$ of 1 mg/l according to the TGD (Part II), equation 70 and 88. Koc value of 1was used.

2.2.2.2.3. PNEC in soil

Tolylfluanid

Acute

- Earthworm (*Eisenia fetida*): LC5 0(14 days)= 78.5 mg/kg ww
- Plants: EC50 (21 d) = 2.44 mg/kg ww

Chronic

- Earthworm (*Eisenia fetida*): NOEC (56 d) = 3.8 mg/kg ww
- Micro-organisms (C-and N-cycle): NOEC (28 d) = 3.3 mg/kg ww

The PNECsoil is 0.076 mg/kg ww. It is derived from the chronic earthworm study by using an AF of 50 according to the TGD (Part II), Table 20. The NOEC from earthworm study compared to micro-organism and plant studies is considered more reliable, because effects on earthworms were seen during the study. In micro-organism and plant studies only two concentrations from the plant protection product point of view were studied and no effects were noticed. Besides, NOECs from earthworms and micro-organisms are more or less the same.

DMST

Chronic
- Earthworm (*Eisenia fetida*): NOEC (56 d) = 9.8 mg /kg ww
- Terrestrial micro-organisms (N-cycle): NOEC (28 d)= 14.1 mg /kg ww

PNECsoil for DMST is 0.196 mg/kg ww. It is derived from the lowest NOEC of the two long term studies by using an AF of 50 according to the TGD (Part II), Table 20.

N,N-DMS

Chronic
- Earthworm (*Eisenia fetida*): NOEC (56 d) = 108 mg /kg ww
- Terrestrial micro-organisms (N-cycle): NOEC (28 d) = 15.24 mg /kg ww
- Springtail (Folsomia candida): NOEC (28 d) = 95 mg/kg ww

PNECsoil for N,N-DMS is 0.3 mg/kg ww. It is derived from the lowest NOEC of 15.24 mg/kg ww by using an AF of 50 according to the TGD (Part II), Table 20.

2.2.2.2.4. PNEC in sewage treatment plant (STP)

Tolylfluanid

PNECSTP of tolylfluanid is set to water solubility level of tolylfluanid, which is 1.0 mg/l (at pH7, at 20°C) . It should be borne in mind that this approach used also for tolylfluanid PT8 assessment is a worst case regarding to agreed approach as outlined in the MOTA (Manual Of Technical Agreements).

DMST

$PNEC_{STP}$ of DMST is 14.3 mg/l. It is derived from EC10 of 143 mg/l by using an AF of 10.

N,N-DMS

$PNEC_{STP}$ cannot be determined for N,N-DMS due to lack of data. Data for N,N-DMS should be submitted for product authorisation phase.

2.2.2.3. PBT and POP assessment

PBT/VPVB ASSESSMENT

Tolylfluanid or any of its degradation products (DMST, DMST-acid, N,N-DMS) are not PBT or vPvB substance according to Commission Regulation 253/2011 amending the Annex XIII of Regulation 1907/2006.

Persistence (P, vP)

Tolylfluanid
DT50 of tolylfluanid in the freshwater/sediment study was in the water 0.6 days at 12°C (0.3 days at 20°C). Tolylfluanid was not detected in the sediment compartment. DT50 of tolylfluanid in soil was 1.5 days at 12 °C (0.8 days at 20°C).

DMST
DT50 of DMST in the freshwater/sediment study was 43 days in water and 91.03 days in sediment at 12 °C. DT50 of DMST in soil was 5.5.days at 12 °C.

DMST-acid
DT50 of DMST-acid in the total freshwater/sediment study was 18.97 days at 12 °C. DMST-acid seems to be an intermediate degradation product. DMST-acid in soil study was <10%.

N,N-DMS
DT50 of N,N-DMS in the freshwater/sediment study was >1896 days in water and sediment at 12 °C. DT50 of N,N-DMS in soil was 1325 days at 12 °C.

Compared to the P-criterion, i.e. DT50 >40 days in freshwater, DT50 >120 days in freshwater sediment and DT50>120 days in soil and also vP-criterion, i.e. DT50> 60days in freshwater and >180 days in soil it can be said that:

- Tolylfluanid does not fulfil P-criterion
- DMST does fulfil P-criterion
- DMST-acid does not fulfil P-criterion
- N,N-DMS does fulfil P-and VP criterion

Bioaccumulation (B, vB)

The experimentally derived BCF_{fish} for tolyfluanid is 74 L/kg (whole fish).

DMST and N.N-DMS do not seem to have potential for bioconcentration either due to their hydrophilic properties and low log Kow (solubility of DMST is 677 mg/l and log Kow 1.99, solubility of N,N-DMS is 140 g/l and log Kow -0.8).

Compared to the B-criterion, i.e. BCF >2000 and vB-criterion > 5000, it can be said that:

- Tolylfluanid and its degradation products do not fulfil B or vB -criterion

Toxicity (T)

The lowest NOEC of tolylfluanid is 0.00265 mg/l (read across from dichlofluanid). The lowest NOEC of DMST and DMST-acid is 1.4 mg/l and N,N-DMS >100 mg/l.

Compared to T-criterion, i.e. NOEC< 0.01 mg/l, criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), toxic for reproduction (category 1A, 1B or 2) or specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation 1272/2008, it can be stated that:

- Tolylfluanid does fulfil T-criterion
- degradation products do not fulfil T-criterion

2.2.2.4. Exposure assessment

Tolylfluanid is intended for use to protect underwater hull of commercial ships as well as pleasure craft. The environmental risk assessment was carried out with the product containing 2.76% tolylfluanid, i.e. 44.63 g/l tolylfluanid in paint. The representative product Interspeed Ultra contains also cuprous oxide 44.35% as active substance, but that has not been assessed in this risk assessment.

Tolylfluanid leaching rate, i.e. 2.01 µg/cm^2/day has been determined with CEPE mass-balance method.

Emissions of tolylfluanid during service life have been calculated to marine and fresh water. Predicted environmental concentrations (PEC) of tolylfluanid and its degradation products in marine water in OECD-EU marina and commercial harbour as well as their surroundings, and OECD-EU shipping lane have been calculated with MAM-PEC 2.5. Emissions to freshwater have been calculated by using OECD-EU marina adjusted to the Swiss marina.

Emissions during application, maintenance and repair of commercial ships and pleasure crafts have been calculated according to the OECD ESD PT21 (European Commission 2004) by using the following scenarios below. Emissions from commercial ships are calculated only to marine surface water in OECD-EU harbour and their surroundings. Emissions to shipping lane and open sea are not calculated due to the high dilution compared to harbour and its surrounding area. Unacceptable risk was detected already in the surrounding areas of harbour. Emissions from pleasure craft are calculated to marine surface water in OECD-EU marina and its surroundings (directly from removal of the paint and indirectly via STP), to STP and to soil depending of the scenario used.

New building:

- Professional application of paint during the new building of commercial ships
- Professional application of paint during the new building of pleasure craft

Maintenance and repair (M&R):

- Commercial ships application by professional
- Pleasure craft application by professionals
- Pleasure craft application by non-professionals

Removal:

- Commercial ships removal of paint by professional
- Pleasure craft removal of paint by professionals
- Pleasure craft removal of paint by non-professionals

In addition to initial PECwater (Tier 1) calculated simply by dividing the daily load (g/day)emitted during paint application or removal with the water volume of harbour or marina without taking into account degradation or water replacement, the Tier 2 approach was used. As decided at the TMIII 2011 and TMIV 2011 Tier 2 PECs are calculated with MAM-PEC 2.5. A daily load (g/d) of tolylfluanid is placed into MAM-PEC and MAM-PEC predictions for concentrations within OECD commercial harbour and marina (Tier 2a) and in the adjacent areas (Tier 2b), have been chosen. PECs of degradation products were calculated with MAM-PEC 2.5.

As agreed at the TMIII 2011 no sediment PEC was needed for tolylfluanid, because tolylfluanid degrades rapidly in water and was not detected in sediment in the water/sediment study. The need for sediment risk assessment was discussed again at TMII 2013, because in the Consolidated Technical Agreement for PT21 a request for sediment risk assessment is said to be also connected to the possible risk from paint particles that may be deposited on the sediment surface where the active substance will be leached out. It was, however, concluded that for tolylfluanid a sediment risk assessment is not needed because unacceptable risk in water in marina and harbour was already detected and RMMs are considered. Besides, PEC/PNEC ratio for sediment and water will be the same if PNEC sediment is calculated based on EPM (equilibrium partitioning method) as would be the case for tolylfluanid, because no study on sediment dwelling organisms was available. It was concluded that the surface water risk assessment can be considered protective enough for sediment dwellers. A long-term sediment dwelling organism study maybe needed in the product authorisation phase if sediment risk assessment is needed to be refined.

Sediment risk assessment was, however, carried out for DMST and N,N-DMS. Both degradation products were detected in sediment >10% in the water-sediment study.

A cumulative risk assessment has been carried out in commercial harbour and marina. As agreed at TMIII 2011 simultaneous exposure from periodic application or removal activities could occur to a commercial harbour and marina which also receives daily inputs via in service releases. Thus, emissions from application or removal stage of commercial ships are summed up with in-service emissions. It was considered that simultaneous releases arising from application and removal activities do not occur. At TMIV 2011 it was decided that emissions via STP are not to be summed up in the cumulative assessment in the harbour. According to the OECD ESD 21 only removal stage of pleasure craft have emissions to marina. Thus, in cumulative risk assessment in the marina removal stage releases are summed up with service-life releases. As done in the cumulative harbour risk assessment STP emissions are not either taken into account in the marina cumulative risk assessment.

According to the OECD ESD PT 21 emissions to soil are only considered for pleasure craft construction and maintenance and repair including removal of the paint. Contrary to OECD ESD PT 21 where PECs soil are calculated based on average daily emission rate over the entire treatment period, PECs in soil have been calculated based on single maintenance cycle as agreed at the TMIII. In these complete maintenance cycles, i.e. 1 day application and 1 day removal of paint of 1 boat, it was assumed that these events are evenly spaced throughout the respective treatment periods to calculate potential accumulation occurring between maintenance cycles. The possible accumulation of residues (active substance) between application & removal events in the whole treatment period was taken into

account by using a multiple application factor (MAF). The initial PEC_{soil} is multiplied with MAF .

2.2.2.5. Risk characterisation

2.2.2.5.1. Sewage treatment plant (STP)

Tolylfluanid and its degradation products, DMST, N,N-,DMS, do not cause unacceptable risk to microbes in a STP from pleasure craft new building and M&R including removal phase. PEC/PNEC ratios of Tolylfluanid are only shown here as they are the worst case values (Table 15). According to the OECD ESD PT21 emissions from commercial ships are not assumed to end up in aSTP.

Table 15. PEC/PNEC ratios for Tolylfluanid in the STP

Tolylfluanid			
Scenario	**PEC_{STP} (µg/l)**	**$PNEC_{STP}$ (µg/l)**	**PEC/PNEC**
Application for new building pleasure craft, worst case	1.9	1000	0.0019
Professional M&R of pleasure craft, worst case	2.9	1000	0.0029
Professional M&R of pleasure craft, typical case	1.2	1000	0.0012
Non-professional M&R of pleasure craft	0.7	1000	0.0007
Professional removal during M&R, worst case	4.9	1000	0.005
Professional removal during M&R, typical case	0.5	1000	0.0005
Non-professional removal during M&R, worst case	0.8	1000	0.0008

2.2.2.5.2. Aquatic compartment (water and sediment)

Direct emissions to marine surface water from new building and M&R including removal activities

Commercial ships in harbours

Tolylfluanid causes unacceptable risk to marine organisms in commercial harbour resulting from commercial ship new building and M&R including removal in the Tier 1 and in the worst case use of Tier 2a assessment (Table16). Risk mitigation methods as a dock floor

discipline, use of containment nets and good spraying practises are needed. Under typical case use of Tier 2a assessment no unacceptable risk was identified.

Table 16. PEC/PNEC of Tolylfluanid from direct emissions to marine water (harbour) from commercial ship new building and M&R including removal

Scenario		PNEC	Worst case		Typical case	
		µg/l	PEC	PEC/PNEC	PEC	PEC/PNEC
New Building application						
Total emission to surface water g/d			13017		2789	
Tier 1	$PEClocal_{dissolved}$ (initial)	$2.65x10^{-2}$	$1.7x10^{-1}$	**6.42**	$3.7x10^{-2}$	**1.40**
Tier 2a	$PEC_{dissolved}$ by MAM-PEC		$8.64x10^{-2}$	**3.26**	$1.85x10^{-2}$	$6.98x10^{-1}$
Tier 2b	$PEC_{dissolved}$ by MAM-PEC in adjacent to harbour		$5.86x10^{-3}$	$2.21x10^{-1}$	$1.26x10^{-3}$	$4.75x10^{-2}$
Application during M&R						
Total emission to surface water g/d			13017		2789	
Tier 1	$PEClocal_{dissolved}$ (initial)	$2.65x10^{-2}$	$1.7x10^{-1}$	**6.42**	0.037	**1.40**
Tier 2a	$PEC_{dissolved}$ by MAM-PEC		$8.64x10^{-2}$	**3.26**	$1.85x10^{-2}$	$6.98x10^{-1}$
Tier 2b	PECdissolved by MAM-PEC in adjacent to harbout		$5.86x10^{-3}$	$2.21x10^{-1}$	$1.26x10^{-3}$	$4.75x10^{-2}$
Removal during M&R						
Total emission to surface water g/d			8926		1294	
Tier 1	$PEClocal_{dissolved}$ (initial)	$2.65x10^{-2}$	$1.19x10^{-1}$	**4.49**	$1.7x10^{-2}$	$6.41x10^{-1}$
Tier 2a	$PEC_{dissolved}$ by MAM-PEC		$5.93x10^{-2}$	**2.24**	$8.59x10^{-3}$	$3.24x10^{-1}$
Tier 2b	PEC dissolved by MAM-PEC in adjacent to harbour		$4.02x10^{-3}$	$1.52x10^{-1}$	$5.83x10^{-4}$	$2.2x10^{-2}$

Degradation products do not cause unacceptable risk to marine organisms in any of the commercial ship scenarios (Table 17).

Table 17. PEC/PNEC ratios of DMST, DMST-acid and N,N-DMS resulting from direct emissions to marine surface water and sediment (harbour) from the new building, M&R including removal of paint of commercial ships

Scenario	**Degradation products**	**PNEC µg/l**	**Worst case**		**Typical case**	
Surface water µg/l			**PEC**	**PEC/PNEC**	**PEC**	**PEC/PNEC**
New building application / Application (M/R)	DMST	1.4x10	$2.66x10^{-1}$	$1.9x10^{-2}$	$5.69x10^{-2}$	$4.1x10^{-3}$
	DMST-acid	1.4x10	$3.58x10^{-3}$	$2.6x10^{-4}$	$7.66x10^{-4}$	$5.5x10^{-5}$
	N,N-DMS	$1.0x10^{3}$	$1.23x10^{-1}$	$1.2x10^{-4}$	$2.62x10^{-2}$	$2.6x10^{-5}$
Removal (M&R)	DMST	1.4x10	$1.82x10^{-1}$	$1.3x10^{-3}$	$2.64x10^{-2}$	$1.9x10^{-3}$
	DMST-acid	1.4x10	$2.46x10^{-3}$	$1.7x10^{-5}$	$3.56x10^{-4}$	$2.5x10^{-5}$
	N,N-DMS	$1.0x10^{3}$	$8.40x10^{-2}$	$8.4x10^{-5}$	$1.22x10^{-2}$	$1.2x10^{-5}$
Sediment (susp.s.) µg/g dw				**PEC/PNEC**	**PEC**	**PEC/PNEC**
New building application / Application (M/R)	DMST	$7.4x10^{-3}$	$5.74x10^{-4}$	$7.8x10^{-2}$	1.23x10-4	$1.7x10^{-2}$
	N,N-DMS	3.7	$3.50x10^{-5}$	$9.4x10^{-6}$	$7.49x10^{-6}$	$2.0x10^{-5}$
Removal (M&R)	DMST	$7.4x10^{-3}$	$3.95x10^{-4}$	$5.3x10^{-2}$	$5.72x10^{-5}$	$7.7x10^{-3}$
	N,N-DMS	3.7	2.40x10-^{5}	$6.4x10^{-6}$	$3.48x10^{-6}$	$9.4x10^{-6}$

Pleasure craft in marinas

Tolylfluanid causes unacceptable risk to marine organisms in marina resulting from removal of paint of pleasure craft in Tier 1 assessment (Table 18). According to the OECD ESD PT21 (Table 4.7, p. 95) only removal phase of pleasure craft emissions are calculated also to the surface water. Risk mitigation methods can be considered, however, the main

focus is on Tier 2a assessment where no risk was identified. Degradation products do not cause unacceptable risk to marine organisms from direct pleasure craft emissions.

Table 18. PEC/PNEC ratios of tolylfluanid, DMST, DMST- acid and N,N-DMS resulting from direct emissions to marine water (marina) and sediment from removal of paint of pleasure craft

Tolylfluanid			**Pleasure craft professionals**				**Pleasure craft non-professionals**	
Removal scenario Marina		PNEC	Worst case		Typical case		Worst case	
		µg/l	PEC	PEC/PNEC	PEC	PEC/PNEC	PEC	PEC/PNEC
Total emission to surface water g/d			3.07		0.31		2.37	
Tier 1	$PEC_{surface\ water}$ dissolved marina	$2.65x10^{-2}$	$3.8x10^{-2}$	**1.43**	$4.0x10^{-3}$	$1.5x10^{-1}$	$3.0x10^{-2}$	**1.13**
Tier 2a	$PEC_{surface\ water}$ dissolved by MAM-PEC		$3.6x10^{-3}$	$1.36x10^{-1}$	$3.7x10^{-4}$	$1.4x10^{-2}$	$2.8x10^{-3}$	$1.1x10^{-1}$
Tier 2b	$PEC_{surface\ water}$ dissolved by MAM-PEC adjacent to marina		$2.9x10^{-5}$	$1.09x10^{-3}$	$3.0x10^{-6}$	$1.13x10^{-4}$	$2.3x10^{-5}$	$8.7x10^{-4}$
Degradation products; only Tier 1 approach was considered			**Pleasure craft professionals**				**Pleasure craft non-professionals**	
Removal scenario Marina		PNEC	Worst case		Typical case		Worst case	
		µg/l	PEC	PEC/PNEC	PEC	PEC/PNEC	PEC	PEC/PNEC
Tier 1 surface water	DMST	14	$2.46x10^{-3}$	$1.8x10^{-4}$	$2.46x10^{-4}$	$1.8x10^{-5}$	$1.9x10^{-3}$	$1.4x10^{-4}$
	DMST-acid	14	$3.37x10^{-4}$	$2.4x^{-5}$	$3.65x10^{-5}$	$2.6x10^{-6}$	$2.55x10^{-4}$	$1.8x10^{-5}$
	N,N-DMS	1000	$1.11x10^{-3}$	$1.1x10^{-6}$	$1.16x10^{-4}$	$1.0x10^{-7}$	$8.54x10^{-4}$	$8.0x10^{-7}$
Tier 1 sediment	DMST	$7.4x10^{-3}$	$5.32x10^{-6}$	$7.2x10^{-4}$	$5.32x10^{-7}$	$7.2x10^{-5}$	$4.12x10^{-6}$	$5.5x10^{-4}$
	N,N-DMS	3.7	$3.18x10^{-7}$	$8.6x10^{-8}$	$3.33x10^{-8}$	$9.0x10^{-9}$	$2.44x10^{-7}$	$6.6x10^{-8}$

Indirect emissions (via STP) to surface water (marina) from pleasure craft new building, M&R including removal activities

Tolylfluanid causes unacceptable risk to marine organisms via STP only in professional worst case application and removal of paint of pleasure craft (Table 19). It should be borne in mind that the PEC-values are very worst case values based on single maintenance events when one boat is painted or paint removed. Thus, the PECs are higher than average values calculated for the whole treatment period and should be considered with caution. Degradation products do not cause unacceptable risk to organisms in water via STP.

Conclusions are the same regarding freshwater organisms if a STP discharges its effluent to freshwater. But as said above, these risk ratios are very conservative and should be considered with caution

Table 19. PEC/PNEC -ratios of Tolylfluanid, DMST, DMST-acid and N,N-DMS in marine water (marina) via STP during application and removal of paint on pleasure craft

Marine marina		**Pleasure craft by professionals**				**Pleasure craft by non-professionals**	
		Worst case		Typical case		Worst case	
Substance	PNEC	PEC	PEC/PNEC	PEC	PEC/PNEC	PEC	PEC/PNEC
New building application							
Tolylfluanid	$2.65x10^{-2}$	$1.9x10^{-2}$	$7.3x10^{-1}$	-	-	-	-
DMST	14	$2.02.48x10^{-2}$	$1.431.77x10^{-3}$	-	-	-	-
DMST-acid		$4.04.8x10^{-3}$	$2.863.42x10^{-4}$	-	-	-	-
N,N-DMS	1000	$1.01.12x10^{-2}$	$1.12x10^{-5}$	-	-	-	-
Application in M&R							
Tolylfluanid	$2.65x10^{-2}$	$2.9x10^{-2}$	**1.09**	$1.2x10^{-2}$	$4.52x10^{-1}$	$6.7x10^{-3}$	$2.53x10^{-1}$
DMST	14	$3.03.7x10^{-2}$	$2.142.64x10^{-3}$	$1.31.55x10^{-2}$	$9.291.1x10^{-3}$	$7.08.7x10^{-3}$	$5.06.2x10^{-4}$
DMST-acid		$6.07.2x10^{-3}$	$4.295.1x10^{-4}$	$3x10^{-3}$	$1.712.1x10^{-4}$	$1.7x10^{-3}$	$1.01.2x10^{-4}$
N,N-DMS	1000	$1.51.68x10^{-2}$	$1.51.7x10^{-5}$	$6.37x10^{-3}$	$6.37x10^{-6}$	$3.53.9x10^{-3}$	$3.53.9x10^{-6}$
Removal of paint in M&R							
Tolylfluanid	$2.65x10^{-2}$	$4.4.9x10^{-2}$	**1.81.85**	$5.0x10^{-3}$	$1.89x10^{-1}$	$8.0x10^{-3}$	$3.02x10^{-1}$
DMST	14	$5.06.2x10^{-2}$	$3.574.4x10^{-3}$	$5.06.2x10^{-3}$	$3.574.4x10^{-4}$	$8.51.05x10^{-2}$	$6.077.5x10^{-4}$
DMST-acid		$1.01.21x10^{-2}$	$7.148.6x10^{-4}$	$1.01.2x10^{-3}$	$7.148.6x10^{-5}$	$1.72x10^{-3}$	$1.211.4x10^{-4}$
N,N-DMS	1000	$2.52.8x10^{-2}$	$2.52.8x10^{-5}$	$(2.52.8x10^{-3}$	$2.52.8x10^{-6}$	$4.34.8x10^{-3}$	$4.34.8x10^{-6}$

Emissions to marine environment from service life stages

Tolylfluanid causes unacceptable risk to marine organisms in the marina during pleasure craft service life (Table 20). Risk mitigation methods are needed. Unacceptable risk was not detected in the surrounding areas of marina.

No unacceptable risk of Tolylfluanid was detected in the harbour and shipping lane from service life stage of commercial ships (Table 20).

Table 20. PEC/PNEC -ratios of tolylfluanid in water (dissolved) in OECD-EU marina, harbour and shipping lane from service life leaching

Scenario	Load	PEC Water (dissolved)	PEC/PNEC Water (dissolved)
	g/d	µg/l	
Tolylfluanid PNEC		**$2.65x10^{-2}$**	
Marina	153	$1.80x10^{-1}$	**6.79**
Marina surroundings		$1.49x10^{-3}$	$5.62x10^{-2}$
Commercial Harbour	2006	$1.31x10^{-2}$	$4.94x10^{-1}$
Commercial harbour surroundings		$9.15x10^{-4}$	$3.45x10^{-2}$
Shipping lane	582	$4.84x10^{-5}$	$1.83x10^{-3}$

Degradation products do not cause unacceptable risk to marine organisms in water or in sediment from service life leaching (Table 21).

Table 21. PEC/PNEC -ratios of DMST, DMST-acid and N,N-DMS in water and sediment (suspended solids) in marina, harbour and shipping lane from service life leaching

Scenario	Load	PEC Water. (dissolved)	PEC Sediment (susp. solids)	PEC/PNEC Water (dissolved)	PEC/PNEC Sediment (susp. solids)
	g/d	µg/l	µg/g dw		
DMST PNEC		**14**	**$7.40x10^{-3}$**		
OECD Marina	95	$1.23x10^{-1}$	$2.66x10^{-4}$	$8.89x10^{-3}$	$3.59x10^{-2}$
OECD Commercial Harbour	1244	$4.09x10^{-2}$	$8.87x10^{-5}$	$4.79x10^{-3}$	$1.20x10^{-2}$
OECD Shipping Lane	361	$3.29x10^{-5}$	$1.50x10^{-7}$	$5.55x10^{-6}$	$8.51x10^{-4}$
DMST-acid PNEC		**14**	**-**		
OECD Marina	18	$1.64x10^{-2}$	-	$1.18x10^{-3}$	-
OECD Commercial Harbour	241	$5.53x10^{-4}$	-	$3.40x10^{-5}$	-
OECD Shipping Lane	70	$4.44x10^{-6}$	-	$3.00x10^{-7}$	-
N,N-DMS PNEC		**1000**	**3.7**		
OECD Marina	43	$5.56x10^{-2}$	$1.59x10^{-5}$	$5.56x10^{-5}$	$4.20x10^{-6}$
OECD Commercial Harbour	562	$1.89x10^{-2}$	$5.40x10^{-6}$	$1.89x10^{-5}$	$1.46x10^{-6}$
OECD Shipping Lane	163	$1.48x10^{-5}$	$8.91x10^{-9}$	$1.48x10^{-8}$	$2.40x10^{-9}$

Emissions to the freshwater environment from pleasure craft service life

Tolylfluanid causes unacceptable risk to organisms in fresh water marina (Swiss harbour) (Table 22). Risk mitigations methods are needed. Unacceptable risk has not been calculated to the surrounding area of the marina, because freshwater marina as such should be considered a protected area. Freshwater marinas are important breeding places for numerous water organisms.

Degradation products do not cause unacceptable risk to water organisms. N,N-DMS concentrations exceed, however, the drinking water standard of 0.1µg/l in the marina. Although, marina is not a water body intended for the abstraction of drinking water, high N,N-DMS concentrations, i.e. 1.71 µg/l, cause concern.

It should be kept in mind that the Swiss marina scenario is not harmonised scenario to be used for antifoulants, but has been used here only because no other freshwater scenario was available and tolylfluanid was first applied also for freshwater used. The applicant has later withtdrawn freshwater use of tolylfluanid due to the concern about contamination of N.N-DMS.

Table 22. PEC/PNEC-ratios of tolylfluanid and its metabolites in water (dissolved) and sediment (suspended solids) in freshwater Swiss marina

	Load g/d	**PEC Water (dissolved) µg/l**	**PEC Sediment (susp. solids) µg/g dw**	**PNEC Water µg/l**	**PNEC Sediment µg/g dw**	**PEC/PNEC Water (dissolved)**	**PEC/PNEC Sediment (susp. solids)**
Tolylfluanid	7.54	0.55	-	0.265	-	**2.1**	-
DMST	4.68	3.63	0.008	140	0.074	0.03	0.11
DMST-acid	0.91	0.016	-	140	-	0.0001	-
N,N-DMS	2.11	**1.71**	0.0005	10 000	37	0.0002	0.00002

In order to restrict freshwater use the applicant has proposed the specific labelling requirement to tolylfluanid containing antifouling product:

"Do not sail in inland (freshwater) water bodies. Do not sail upstream river harbors or yards adjacent to estuarine mouth with your boat treated with tolylfluanid containing antifouling product".

According to the applicant the principle of respective labeling is a well-known mitigation measure and practiced for many dangerous substances or mixtures thereof which are sold to the public. Potential customers will read the label carefully before they buy the product. They will decide for an alternative product without Tolylfluanid, which suits better their requirements, if they intend to sail in freshwater bodies with their boats.

In addition, paints with tolylfluanid will disappear from local markets in areas with recreational lakes, reservoirs or upper freshwater river parts. Shop owners are not expected to have products on their shelves for which there is no legal local market.

Practical surveillance of the restriction is also made easy with this additional labeling. With the restriction for sailing in freshwater bodies on the label, paints should be available in shops close to coastal areas only and surveillance authorities should not find the products in shops close to inland water bodies.

As a further measure to support the label restriction, the sales packaging of the paint can be equipped with a self-adhesive sticker, reading also above sentence. The self-adhesive sticker is intended to be placed near the control device of the boat, within visual range of the coxswain and serves as aid recall of the restriction.

This type of measure is legally enforced for low speed automobile tires in Germany (§ 36 of Strassenverkehrs-Zulassungs Ordnung, StVZO). If M + S tires with approval for a maximum speed below the specification as stated in vehicle registration certificate are mounted on a car, than a sticker needs to be placed within the driver's field of view. The sticker states the maximum speed which is allowed to drive only, according to the approved velocity of the tires.

Aggregated exposure marine exposure (harbour and marina)

For aggregated exposure of commercial ships, unacceptable risk of tolylfluanid was identified in commercial harbour in all scenarios but not in typical case situations where removal releases were summed up with service-life releases (Table 23). Risk mitigation methods like a dock floor discipline, use of containment nets and good spraying practices are needed for the commercial harbour and can be taken into account for tolylfluanid.

In surrounding areas of harbour (wider environment), however, no unacceptable risks were identified. Thus, a safe use exists for the purpose of recommending approval of active the substance as agreed at TMIII 2011.

Table 23. Tolylfluanid cumulative PEC/PNEC -ratios from emissions from commercial ships in the harbour and its surrounding areas

Tolylfluanid		**Worst case**		**Typical case**	
Scenario	PNEC $\mu g.l^{-1}$	PEC $\mu g.l^{-1}$	PEC/PNEC	PEC	PEC/PNEC
Application + in-service emissions		15023 g/d		4795 g/d	
In commercial harbour (Tier 2a)	0.0265	0.0997	**3.76**	0.0318	**1.20**
Surroundings of commercial harbour (Tier 2b)	0.0265	0.0068	0.255	0.0022	0.083
Removal + in-service emissions		10932 g/d		3300 g/d	
In commercial harbour (Tier 2a)	0.0265	0.0726	**2.74**	0.0219	0.83
Surroundings of commercial harbour (Tier 2b)	0.0265	0.0049	0.18	0.0015	0.06

For aggregated exposure of pleasure craft, unacceptable risk of tolylfluanid was identified to marine organisms in the marina when emissions from removal of paint and from service life of pleasure craft are summed up (Table 24).

Common general risk mitigation methods for pleasure craft are still under preparation. At TMII 2012 the antifouling industry promised to give more information to member states on IPPC rules as well as practical examples. According to the antifouling industry a lot of activities are carried out in boatyards and marinas, which are regulated by the IPPC rules. The code of practices and best practice are incorporated within BREFs (the Best Available Techniques (BAT) reference documents) which are related to the IPPC directive.

According to the applicant dock yard and boatyard abatement systems (e.g. removing waste paint and flakes from beneath the vessel, filtering waste washing water etc) will minimise the emission of antifouling paint to the environment. Therefore, the worst case scenarios are unlikely to be realized at facilities in the Europe. The FI CA is of the opinion that there are local yacht clubs and marinas which have adopted and implemented proper risk mitigation methods to reduce emissions to the environment. However, there are plenty of marinas and winter storage yard which do not have sufficient methods in use. According to the applicant paint releases which enter the soil will not spread but rapidly dry under a build up of paint flakes. These flakes can easily be collected afterwards and disposed as waste. If they stay on the ground a slow release of the active must be assumed after rain events.

Unacceptable risk was not detected in the surrounding areas of the marina (Tier 2b), wider environment. Thus, a safe use exists for the purpose of recommending approval of tolylfluanid as agreed at TMIII 2011.

Table 24. Tolylfluanid cumulative PEC/PNEC -ratios from emissions from pleasure craft in the marina and its surrounding areas

Tolylfluanid		**Pleasure craft removal professional use**				**Pleasure craft removal non-professional use**	
		Worst case		**Typical case**		**Worst case**	
Scenario	PNEC $\mu g.l^{-1}$	PEC $\mu g.l^{-1}$	PEC/PNEC	PEC $\mu g.l^{-1}$	PEC/PNEC	PEC $\mu g.l^{-1}$	PEC/PNEC
Removal + in-service emissions		156.07 g/d		153.31 g/d		155.37 g/d	
In Marina (Tier 2a)	0.0265	0.184	**6.943**	0.18	**6.792**	0.18	**6.792**
Surroundings of marina (Tier 2b)	0,0265	0.0015	0.057	0.0015	0.057	0.0015	0.057

2.2.2.5.3. Terrestrial compartment

Tolylfluanid causes unacceptable risk to soil organisms in all single maintenance period (Table 25). Cumulative risks (= tolylfluanid total concentrations) are only a little bit higher than the initial risks. Risks are the highest after professional use. In addition, DMST causes unacceptable risk to soil organisms, but no risks were identified for N,N-DMS.

In order to prevent soil contamination risk mitigation methods are needed for tolylfluanid. During antifouling painting and removal of paint the soil must be protected (covering or sealing the soil) to prevent spills to the environment. The possible contamination of the groundwater during painting and removal of the paint can be prevented when emissions to the soil are prevented.

According to the applicant dock yard and boatyard abatement systems (e.g. removing waste paint and flakes from beneath the vessel, filtering waste washing water etc.) will minimise the emission of antifouling paint to the environment. Therefore, in practice the worst case scenarios are unlikely to be realized at facilities in Europe. In addition, it can be assumed that the paint which enters the soil will not spread but rapidly dry into paint flakes. These flakes can easily be collected and disposed as a waste. If they stay on the ground a slow release of the active must be assumed after rain events.

Table 25. PEC/PNEC -ratios of tolylfluanid, DMST and N,N-DMS in soil from pleasure craft single maintenance periods

Scenario		**Substance**	**PEC [mg/kg ww soil]**	**PNEC [mg/kg ww soil]**	**PEC/PNEC**
New Building single maintenance period application	Worst case	Tolylfluanid initial	1.105	0.076	**14.54**
		Tolylfluanid total	1.114		**14.66**
		DMST	0.48	0.196	**2.45**
		N,N-DMS	0.088	0.3	0.29
	Typical case	No emission	-	-	-
Professional use single maintenance period (1d application + 1 day removal of 1 boat)	Worst case	Tolylfluanid initial	2.741	0.076	**36.07**
		Tolylfluanid total	3.094		**40.71**
		DMST	1.206	0.196	**5.15**
		N,N-DMS	0.219	0.3	0.73
	Typical case	Tolylfluanid initial	0.680	0.076	**8.95**
		Tolylfluanid total	0.767		**10.09**
		DMST	0.299	0.196	**1.53**
		N,N-DMS	0.054	0.3	0.18
Non-professional use single maintenance period (1 day application + 1 days removal of 1 boat)	Typical case	Tolylfluanid initial	0.845	0.076	**11.12**
		Tolylfluanid total	0.845		**11.12**
		DMST	0.372	0.196	**1.90**
		N,N-DMS	0.068	0.3	0.23
	Worst case	No emission	-	-	-

2.2.2.5.4. Groundwater

Risks to groundwater were assessed only for N,N-DMS, which is a very mobile and persistent metabolite (Table 26). Based on the PEARL 3.3.3 calculation by the applicant the groundwater limit concentration of 0.1µg/l was exceeded in the Jokioinen scenario, i.e. 0.114 µg/l. It should be emphasized that it is rather unlikely that groundwater is intended for the abstraction of drinking water directly below grounds of industrial area, i.e. new building facility. Anyway, emissions to the ground should always be prevented. There are risk mitigations methods available, e.g. covering the ground with plastic sheet and removal of paint waste to appropriate disposal, which are to be used. Evidently, restrictions and regulations for these kinds of industrial facilities come also from the IPPC directive.

Table 26. $PEC_{groundwater}$ of N,N-DMS (µg/L) after application of tolylfluanid as antifouling substance to pleasure crafts, simulated with PEARL 3.3.3

Scenario	New building application of paint, (mixed airless spray/brush & roller) professionals, worst case [µg/l]	New building application of paint, (brush & roller) professionals, worst case [µg/l]
Chateaudun	0.077	0.032
Hamburg	0.078	0.032
Jokioinen	**0.114**	0.048
Kremsmuenster	0.058	0.024
Okehampton	0.053	0.022
Piacenza	0.052	0.022
Porto	0.039	0.016
Sevilla	0.047	0.019
Thiva	0.051	0.021

2.2.2.5.5. Atmosphere

Tolylfluanid and DMST are not expected to partition to the atmosphere to any significant extent due to their low vapour pressure and short chemical lifetime in air. The vapour pressure of tolylfluanid is 2×10^{-4} Pa, DMST 2.5×10^{-4} Pa and N,N-DMS 1.8×10^{-6}. On the basis of Henry's law constant (7.7×10^{-2} Pa/ m^3/mol) tolylfluanid has a certain, albeit low tendency to volatilise from aqueous solutions. However, the hydrolysis of tolylfluanid is so rapid, that volatilisation is not of concern for the distribution of tolylfluanid in the environment. Based on the low Henry`s law constant of DMST (7.7×10^{-5} Pa/m^3/mol) and N,N-DMS (1.6×10^{-7} Pa /m^3/mol) have no tendency to volatilise aqueous solutions.

Tolylfluanid is not expected to have long-range transport potential because estimated tolylfluanid photochemical half-life of 21.5 hours is below the criterion of 2 days given for persistent organic pollutants (POP) as defined in the Annex D of the Stockholm Convention 2001.

The RIVM has estimated the effects of atmospheric deposition of pesticides on terrestrial organisms from existing data (Jong & Luttik 2003). Both calculations of RIVM and measurements of pesticide deposition carried out by TNO provided input to the RIVM estimation of deposition. Estimations for the substance Tolylfluanid (in RIVM report) do however not rely on measurements for the substance. In the RIVM report it is furthermore given that calculations neglected degradation of substances. In the TNO report information about the measured substances is given, Tolylfluanid was not among them. For the purpose of Tolylfluanid antifouling uses the RIVM report is thus regarded as not relevant.

Furthermore, due to the special characteristics of antifouling paints, these are products of high specific density. When sprayed (the only possibly relevant use regarding air pollution) the heavy droplets will settle in the direct vicinity of the application area.

2.2.2.5.6. Risk for secondary poisoning

Tolylfluanid and its degradation products, i.e. DMST, DMST-acid, N,N-DMS do not show a intrinsic potential for bioconcentration in organisms that could lead further to secondary poisoning. Tolylfluanid is rapidly degraded in water and soil. DMST and DMST-acid degrade also in water and soil and their log Kow-values are very low. Contrary to other degradation products N,N-DMS is persistent in soil and water, but its log Kow is negative and it has not shown any adsorption to soil so that log Koc was not possible to determine. Besides, all degradation products show low toxicity to organisms compared to tolylfluanid.

2.2.2.5.7. Monitoring and modelling data

Several monitoring studies are available for N,N-DMS and DMST and these are refered to here. The applicant has also submitted monitoring data on dichlofluanid containing antifouling paints in several seawater marinas, but these studies are not referred to. The results can be, however, considered also for tolylfluanid after the RMS UK has finalised risk assessment of dichlofluanid.

<u>Monitoring in the Netherlands</u>
The monitoring data in Dutch water (2007-2008) clearly shows that N,N-DMS is present in waters. In recreational lakes and marinas DMSA (degradation product of dichlofluanid) was measured at concentrations of 17 ng/l up to approximately 1000 ng/l. N,N-DMS was found in concentrations between 290 and 2250 ng/l. DMST was not detected at all (<LOQ of 10 ng/l) which was not a surprise, because tolylfluanid is not used yet as an antifouling product. Due to the agricultural use of tolylfluanid N,N-DMS may have been expected to reach surface water in relevant amounts via soil and groundwater, but concentrations of N,N-DMS are evidently only from dichlofluanid antifouling use. Highest N,N-DMS concentration was obtained from surface water in a marina, lowest values in lake waters.

Concentrations do not indicate concern to the environment, i.e. water organisms, but concentrations of N,N-DMS cause concern regarding human health. N,N-DMS concentrations may be expected to accumulate in enclosed freshwaters with limited water flow and marinas with high numbers of boats moored. Although these kinds of places are not used for production of drinking water, the drinking water standard of 0.1 µg/l is exceeded (Drinking water Directive 98/83/EC).

Monitoring of untreated and treated raw water and drinking water in the Netherlands showed that N,N-DMS concentrations can exceed the value of 0.1 µg/l in surface water intended for the abstraction of drinking water. In drinking water NDMA concentrations were rarely detected, although there is a clear relationship between ozone treatment and formation of NDMA. Only two occasions NDMA concentrations of 1 ng/l and 2 ng/l (LOQ=1) were detected. Apparently most of the NDMA is removed from the water by post-ozone treatment.

Monitoring in Norway

Based on the screening study carried out in 2011-2012 in two lakes close to Oslo N,N-DMS concentrations were 456-774 ng/l in the ØstensjØ and 104-540 ng/l in the Holmendammen lake. Both lakes receive runoff from a large residential area and also from woodlands used for recreation. In the control lake situated in the remote mountains concentrations of N,N-DMS were below the limit of detection of 5ng/l (Langford 2012).

Monitoring in Sweden

Tolylfluanid has been monitored in the Swedish screening program of 2007 SWECO Environment in different matrices, but detected only on two occasions in conncetion to a major point source (a paint industry). Tolylfluanid was detected in the sediments of two storm water manholes at a paint industry (0.26 and 0.85 mg/kg) and in soil (0.3 mg/kg) at a storage site for treated wood. Degradation products were not monitored (Törneman et al. 2009).

Modelling of surface water by Royal Haskoning

Modeling for a product containing 4.04% tolylfluanid shows that N,N-DMS concentrations can exceed the value of 0.1 µg/l in the surface water. The most relevant factors influencing the concentrations are the number of boats in a lake, flushing rate of the lakes (the higher the flushing rate the lower the concentrations) and the market share. When the emission (number of boats/ships) is considered constant, the most important factor determining N,N-DMS equilibrium concentration in water system are the market share and flushing rate (=residence time of water) .

Based on modeling and monitoring the following factors influence the N,N-DMS concentrations and may cause concern regarding the drinking water use:

- surface water is intended for the abstraction of drinking water
- freshwater source with low water exchange (flush rates) and high residence time
- high boat traffic with high market share of dichlofluanid/tolylfluanid containing products

According to the Applicant risk for production of drinking water from rivers close to the coastal area is assumed to be low due to the following reasons:

- in most cases water is subject to tidal influences and thus it is not freshwater, but estuarine water (e.g. rivers Thyne, Thames, Elbe)
- harbours and yards in many rivers serve as home ports and yards for yachts and ships sailing most of the time in marine or estuarine water bodies. The downstream river parts serve as connecting lanes between the harbours/yards and the coast. If boat traffic is high, extraction of surface water for production of drinking water at these locations is very unlikely.
- If boat traffic is low: dilution of N,N-DMS in rivers is high (high flow rates and low water residence time).

Conclusion: It is unlikely that surface water with high boat traffic (i.e. harbours, lakes, canals with high boat density) is intended for the abstraction of drinking water. Also risk is assumed to be low in water bodies with high flow rates or short water residence time (rivers, especially close to estuarine area, also lakes with high flow rate) due to the dilution. Uncertainties remain, however, for N,N-DMS in specific water bodies which are not covered by the descriptions above. Thus, it cannot be excluded that N,N-DMS values from antifouling leaching in service uses may exceed the drinking water standard of 0.1µg/l in water bodies intended for the abstraction of drinking water. Risk mitigations methods are therefore needed.

2.2.3. Assessment of endocrine disruptor properties

Tolylfluanid is not included in the priority list of substances for further evaluation of their role in endocrine disruption established within the Community Strategy for Endocrine Disrupters (COM (1999) 706, COM (2001) 262). Available evidence at this time indicates that tolylfluanid and its degradation products do not have endocrine-disrupting properties (classification criteria specified in Art. 5(3) of Regulation 528/2012 are not met, no effects on endocrine organs and/or reproduction were observed in standard toxicity studies to raise a concern for potential endocrine disruption).

2.3. Overall conclusions

The outcome of the assessment for tolylfluanid in product-type 21 is specified in the BPC opinion following discussions at the 6th meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA web-site.

2.4. Data requirement for the representative product

- The efficacy of the individual antifouling products shall be demonstrated prior to product authorisation at the Member State level
- Leaching test of the individual antifouling products shall be submitted prior to product authorisation at the Member State level
- According to the EU waste legislation waste antifouling products are considered

hazardous waste. Therefore, application solutions must be collected and reused or disposed of as hazardous waste and they must not be released to soil, surface water or any kind of sewer.

- Due to a possible risk for children touching wet paint on boats, also oral exposure after hand-to-mouth contact shall be evaluated at product authorisation stage depending on discussions at the ad hoc Working group on Human Exposure. If an unacceptable risk is identified, the suitability of the label phrase 'Keep children away from treated surfaces until the surfaces are dry.' should be assessed.

- Storage stability study for two years at ambient temperature.

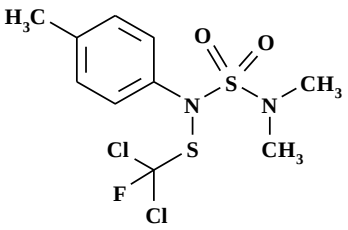
APPENDIX 1: LISTING OF END POINTS

Tolylfluanid including DMST, DMST-acid and N,N-DMS

Chapter 1: Identity, Physical and Chemical Properties Classification and Labelling

Active substance (ISO Common Name)	Tolylfluanid
Product- type	21

Identity

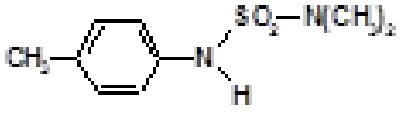
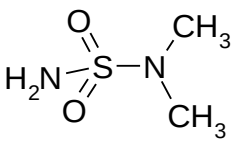
Chemical name (IUPAC)	N-(Dichlorofluoromethylthio)-N',N'-dimethyl-N-p-tolylsulfamide
Chemical name (CA)	Methanesulfenamide, 1,1-dichloro-N-[(dimethylamino)sulfonyl]-1-fluoro-N-(4-methylphenyl)-
CAS No	731-27-1
EC No	211-986-9
Other substance No.	CIPAC No. 275
Minimum purity of the active substance as manufactured (g/kg or g/l)	≥ 960 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	none
Molecular formula	$C_{10}H_{13}Cl_2FN_2O_2S_2$
Molecular mass	347.3
Structural formula	

Physical and chemical properties

Melting point (state purity)	93°C (purity:99.9%)
Boiling point (state purity)	Not measurable, substance decomposes at > 200°C (purity: 99.9%)
Temperature of decomposition	DTA: Exothermic reaction above 200 °C. TGA-measurement: Weight loss observed above 150 °C under air and nitrogen. (purity:99.9%)
Appearance (state purity)	Physical state: solid Colour: colourless crystals (purified a.i.) colourless chrystalline powder with lumpy parts (techn.) (purities not specified) Odour: odourless (purified a.i.). Weak characteristic acidulous, musty smell (techn.) (purities not specified)
Relative density (state purity)	1.530 g/cm³ at 20°C (purity: 99.9%)
Surface tension	70 mN/m at 20°C (measurements in the range of concentrations of 0.64-0.96 mg/l); not surface active (99.0%)
Vapour pressure (in Pa, state temperature)	2×10^{-4} Pa at 20°C (extrapolated); 4×10^{-4} Pa at 25°C (extrapolated) (purity: 99.9%)
Henry's law constant (Pa m^3 mol^{-1})	6.6×10^{-2} Pa· m³· mol^{-1}
Solubility in water (g/l or mg/l, state temperature)	pH__5____: see below (pH 4)
	pH__9____: see below (pH 4)
	pH__4____: 0.65 mg/l at 10°C, 1.04 mg/l at 20°C, 1.52 mg/l at 30°C; (purity:99.9%) The solubility in water is independent from pH in the range of pH 4 to pH 9.
Solubility in organic solvents (in g/l or mg/l, state temperature)	Results at 20ºC (purity 99.0%): 1-octanol 16 g/l 2-propanol 22 g/l n-heptane 54 g/l polyethylene glycol 56 g/l xylene 190 g/l acetone > 250 g/l acetonitrile > 250 g/l dichloromethane > 250 g/l dimethylsulfoxide > 250 g/l ethylacetate > 250 g/l
Stability in organic solvents used in biocidal products including relevant breakdown products	Tolylfluanid was stable for 8 weeks at 40 °C in a test for storage stability of a solvent-based wood preservative
Partition coefficient (log P_{OW}) (state temperature)	Log K_{ow} = 3.9 at 20 °C (99.9%) This value is considered as independent of pH, in the pH range of 4 -9

Hydrolytic stability (DT_{50}) (state pH and temperature)	See Chapter 4: Fate and Behaviour in the environment
Dissociation constant	Tolylfluanid shows in aqueous solvents neither acidic nor basic properties (in the range pH 4 to pH 9). pK value is not possible to specify. (99.9%)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	UV/VS measured in methanol gave absorption maximum at 210 nm. No absorbance above 290 nm. (99.9%)
Photostability (DT_{50}) (aqueous, sunlight, state pH)	As the UV absorption data showed that in aqueous solution tolylfluanid did not absorb any light at wavelengths above 290 nm, the molar extinction coefficient was calculated to be <10. Therefore, the determination of the quantum yield was not required. Even under assumption of a quantum yield of 1 the assessment of the environmental half-life by means of computer models would yield values of several years.
Quantum yield of direct phototransformation in water at Σ > 290 nm	See above
Flammability	The test substance is not highly flammable. No self ignition at temperatures up to melting point (93 °C) (97.7%)
Explosive properties	Test substance is not explosive. (97.1%)
Oxidizing properties	Test substance is not oxidizing (97.1%)

Identity and physical and chemical properties of DMST and N,N-DMS

Active substance (ISO Common Name)	Dimethylsulfotoluidid (DMST)	N,N-dimethylsulfamide (N,N-DMS)
Chemical name (CA)	N,N-dimethyl-N'-p-tolyl-sulfamide	Sulfamide, N,N-dimethyl-
CAS No	66840-71-9	3984-14-3
Molecular formula	$C_9H_{14}N_2O_2S$	C2 H8 N2 O2 S
Molecular mass	214.3 g/mol	124.16
Structural formula		

Vapour pressure	2.5 × 10^{-4} Pa at 20 °C (94.9%) (extrapolated)	1.8 x 10E-6 hPa at 20°C 7.2 x 10E-6 hPa at 25°C (98.1%)
Henry´s Law Constant	7.7E-05 Pa·m^3·mol^{-1} at 20 °C	1.34 x 10E-7 Pa m³/mol (pH 5), 1.60 x 10E-7 Pa m³/mol (pH 7), 1.35 x 10E-7 Pa m³/mol (pH 9) (n.a)
Solubility in water	677 mg/l at 20 °C (94.95%)	pH5:167 g/L at 20°C pH 9:165 g/L at 20°C pH 7:140 g/L at 20°C (98.1%)
Partition coefficient n-octanol/water	log K_{ow} = 1.99 at 20 °C (99.8%)	pH 5: -0.8 at 20°C pH 9: -0.9 at 20°C pH 7: -0.8 at 20°C (98.1%)
Dissociation constant		10.6 (98.1%) (non-GLP study)

Classification and proposed labelling of tolylfluanid

with regard to physical/chemical data	No classification required
with regard to toxicological data	**as in Directive 67/548/EEC** If tolylfluanid is not respirable to a toxicologically significant amount (containing < 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm, Index No.613-116-01-4), the classification shall be the following Xi: Irritant; R 36/37/38: Irritating to eyes, respiratory system and skin R 43: May cause sensitisation by skin contact; If the substance is respirable to a toxicologically relevant amount (containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm, Index No. 613-116-00-7), the classification shall be the following: T+: Very toxic R 26: Very toxic by inhalation; R 48/23: Toxic: danger of serious damage to health by prolonged exposure through inhalation; R 36/37/38: Irritating to eyes, respiratory system and skin; R 43: May cause sensitisation by skin contact;

	According to Regulation 1272/2008 Index No 613-116-01-4 tolylfluanid (ISO); dichloro-*N*-[(dimethylamino)sulphonyl]fluoro-*N*-(*p*-tolyl)methanesulphenamide; [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]:
	Eye Irrit. 2 — H319 STOT SE 3 — H335 Skin Irrit. 2 — H315 Skin Sens. 1 — H317
	Index No 613-116-00-7 tolylfluanid (ISO); dichloro-*N*-[(dimethylamino)sulphonyl]fluoro-*N*-(*p*-tolyl)methanesulphenamide; [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]:
	Acute Tox. 2 * — H330 STOT RE 1 — H372** Eye Irrit. 2 — H319 STOT SE 3 — H335 Skin Irrit. 2 — H315 Skin Sens. 1 — H317
with regard to fate and behaviour data	No classification required
with regard to ecotoxicological data	**as in Directive 67/548/EEC** N; Dangerous for the environment R 50: Very toxic to aquatic organisms Specific concentration limit: N; R50: C ≥ 2,5 %
	According to Regulation 1272/2008
	Hazard class and category codes: Aquatic Acute 1 — H400; Aquatic Chronic 2 — H411
	Hazard statement codes: H410: Very toxic to aquatic life with long lasting effects.

Specific concentration limits, M-factors	M=10 (Aquatic Acute 1)

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) Impurities in technical active substance (principle of method)	Tolylfluanid and organic impurities quantified by reverse phase HPLC (Spherisorb ODS 2, 125 mm x 4.0 mm, 3 µm) with gradient elution and using external standardisation and DAD detector. Inorganic substances: titration of sample solution with silver nitrate solution to ascertain the chloride content and the content of magnesium is determined from an external standard calibration curve by Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES).

Analytical methods for residues

Soil (principle of method and LOQ)	Soil samples were cleaned up by GPC and purified (not for DMST) using silica gel columns. The concentrated extracts were analysed using capillary gas chromatography (DB-5 MS) with mass selective detection (MSD). The MS ion m/z 238, 137 and 181 is used for quantification. For DMST MS ion m/z 214 and 106 is used for quantification. LC-MS/MS was additionally used for DMST for confirmation with m/z 106. LOQ for tolylfluanid and DMST in soil is 0.01 mg/kg.
Air (principle of method and LOQ)	Air is passed through Tenax- or XAD-2 adsorption tubes with a rate of 2 l/min for 6 hours. The adsorbed active substance is extracted with n-butylacetate and determined by gas chromatography using a capillary column and a N/P-specific detector. Confirmatory method for quantitation of tolylfluanid residues in air is based on gas chromatography using a capillary column and a mass selective detector (MSD). In the selected ion monitoring mode, two individual ions at m/z = 137 and 238 are used for detection. Lower limit of quantification: 0.01 mg a.i. /m^3 air.
Water (principle of method and LOQ)	Prior to analysis formic acid is added to the drinking and surface water samples to a final concentration of 1 ml/l. Acidified samples are directly injected into the HPLC-MS/MS. Residues of tolylfluanid and DMST were

	determined by HPLC (Phenomenex Aqua®, 150 mm x 2 mm, 5 µm column; gradient eluation) using turbo-ionspray interface and mass selective detector (MS/MS). The method was validated for two mass transitions of tolylfluanid (m/z 346.9 → 237.8 and m/z 346.9 → 137.0) as well as DMST (m/z 214.9 → 106.0 and m/z 214.9 → 79.0). LOQ for tolylfluanid and DMST in surface and drinking water is 0.05 µg/l.
	Metabolite **N,N-dimethylsulfamide,** Reversed phase HPLC-MS/MS. LOQ = 0.025 µg/l
Body fluids and tissues (principle of method and LOQ)	n.a.Blood sample is hemolysed using ultrasonic vibration. A portion of acetone is added and after centrifugation, the supernatant is transferred onto an extraction column filled with kieselguhr. The column is eluted with a mixture of ethyl acetate / dichloromethane and with hexane. After addition of toluene, the eluate is concentrated. The internal standard bromophosmethyl is added and the solution is made up to the final volume with toluene. The LOQ of the blood method is 50 ng/mL. Additional validation data including precision and accuracy are required. Methods for the other relevant body tissues with sufficient validation should be submitted, or a justification. Data must be provided 6 months before the date of approval to the evaluating eCA.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	n.a.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Sample material is extracted with acetone. Water is added beforehand in an amount that takes full account of the natural water content of the sample so that during extraction the acetone:water ratio remains constant. For liquid-liquid partition ethyl acetate/cyclohexane and sodium chloride is added. After repeated mixing excess water is separated. The evaporated residue of an aliquot of the organic phase is cleaned up by gel permeation chromatoraphy using a mixture of ethyl acetate / cyclohexane as eluant and an automated gel permeation chromatograph. The residue containing fraction is concentrated and analysed by gas chromatography using fused silica capillary

	column and an electron capture detector. The LOQs of the methods are 0.01 - 0.05 µg/L . A fully validated method, including the linear range and the specificity, for fish and shellfish matrices shall be submitted for tolylfluanid 6 months before the date of approval to the evaluating Competent Authority (eCA).
Sediment	Analytical methods developed and validated for soil(s) can be used for sediments without or with only marginal modifications which may also be necessary for individual soils. It is a matter of pre-validation of a method prior using it for sample analysis to figure out its suitability and to determine adjustments which are necessary to fulfill the acceptance criteria for validation. After conducting of the environment risk assessment the RMS is not considering the sediment method necessary.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Rat: ^{14}C ring labelled tolylfluanid: 95%; t_{max} in plasma < 3 hours
	Rat: ^{14}C labelled fluorodichloromethyl sulphenyl group: 70–80%; t_{max} in plasma < 3 hours
Rate and extent of dermal absorption for the active substance:	Final agreement on tolylfuanid as a plant protection product states that the dermal absorption is 5 % for the concentrate and 7 % for the 1:100 dilution (see DocIIA). Based on this, **10 % can be used** for dermal absorption in calculations of dermal absorption in the absence of solvent, e.g. in secondary exposure, as a moderately conservative value**.** In vitro dermal absorption study in human epidermis using **a mineral-oil based formulation** of tolylfluanid (0.7% by weight) was applied for 6 h. The absorbed dose after 24 h was **71.19%.**
Rate and extent of the dermal adsorption for the representative product(s):	The value of 3.3 % has been used for dermal absorption in risk assessment , based on an in vitro dermal absorption study in human epidermis
Distribution:	Highest concentrations in the excretory and metabolically active tissues (liver and

	kidney). A high relative concentration was also found in thyroid of male rats.
Potential for accumulation:	No. Tolylfluanid was not found to accumulate in the carcass or carcass minus gastrointestinal tract.
Rate and extent of excretion:	Renal excretion (48 h): 50-60% ([dichloro-fluoromethyl-^{14}C]) and roughly 60-90% ([phenyl-UL-^{14}C]) of the administered radioactivity. Biliary excretion (48 h): 22-30% ([dichloro-fluoromethyl-^{14}C]) and 12-36% ([phenyl-UL-^{14}C]) of the administered radioactivity.
Toxicologically significant metabolite	Dimethylaminosulfotoluidide (DMST, N,N-dimethyl-N'-(4-methylphenyl)-sulfamide)

Acute toxicity

Rat LD_{50} oral	> 5000 mg/kg bw (males + females)
Rat LD_{50} dermal	> 5000 mg/kg bw (males + females)
Rat LC_{50} inhalation	Micronized dust, MMAD 2.1-2.5 µm: 200/160 mg/m^3/4 h (m/f) Technical dust, MMAD: 16.8-19.8 µm: > 1038 mg/m^3/4 h (m+f) Liquid aerosol, MMAD: 3.39 $\pm$ 1.96 µm: > 770 mg/m^3 air a.i./4h (m+f)
Skin irritation	Irritating to skin
Eye irritation	Irritating to eyes
Skin sensitization (test method used and result)	Sensitising (Magnusson-Kligman test)

Repeated dose toxicity

Species/ target / critical effect	Dog – liver (weight increase, histopathological alterations), kidney (nephropathy and disturbance of kidney function), thyroid (increased weight)
Lowest relevant oral NOAEL (short term)	33 mg/kg bw/day (subchronic dog)
Lowest relevant oral NOAEL (long term)	18 mg/kg bw/day (two-year rat)
Lowest relevant dermal NOAEL	Systemic: ≥ 300 mg/kg bw/day (highest dose tested) Topical: < 1 mg/kg bw/day (subacute rabbit)
Lowest relevant inhalation NOAEL	1 mg/m³ (4 weeks, rat)

Genotoxicity	Tolylfluanid is not proposed to be classified as mutagenic, based on the overall *in vivo* data pointing towards negative results, although some clear or equivocal genotoxicity test results were encountered in the sole acceptable *in vitro* chromosome aberration tests and in some of the tests for gene mutations in mammalian cells.

Carcinogenicity

Species/type of tumour	Rat / thyroidal follicular cell adenoma (not relevant for humans, rat-specific aetiology)
lowest dose with tumours	504–584 mg/kg bw/day

Reproductive toxicity

Species/ Reproduction target / critical effect	Rat, two-generation. Pups, reduced body weight and spleen weight
Lowest relevant reproductive NOAEL	14 - 31.5 mg/kg bw/day
Species/Developmental target / critical effect	Rabbit / Embryo (teratogenicity): increased resorptions; foetuses: increased number of malformations; does: hepatotoxicity
Lowest relevant developmental NOAEL	25 mg/kg bw/day
Species/Developmental target / critical effect	Rat (teratogenicity, 2nd spec): developmental effects
Lowest relevant developmental NOAEL	$\geq$ 1000 mg/kg bw/day

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Tolylfluanid did not show any signs of delayed neurotoxicity in subchronic or chronic studies with repeated dosage.
Lowest relevant developmental NOAEL / LOAEL.	≥ 620 mg/kg bw/day (subchronic rat)

Other toxicological studies

....	No indications for special concern.

Medical data

....	A few cases of allergic skin reactions are described among manufacturing plant personnel. As these occurred at plants where a structurally related substances are

produced and formulated, the reactions can not be attributed only to tolylfluanid.

Summary (Annex IIA, point 6.10)	Value	Study	Safety factor
ADI (if residues in food or feed)	0.1 mg/kg bw /day	as in PPP, 2-generation rat	100 and rounding
AEL short term (Non-professionals)	0.25 mg/kg bw/day	rabbit teratogenicity	100
AEL medium term (Professionals)	0.18 mg/kg bw/day	2-year rat oral	100
AEL long term (Professionals)	0.18 mg/kg bw/day	2-year rat oral	100
Drinking water limit	0.1 µg/L	as set by EU Drinking Water Directive	not relevant
ARfD (acute reference dose)	0.25 mg/kg bw/day	rabbit teratogenicity	100

Acceptable exposure scenarios (including method of calculation)

Primary exposure - professional use;	
Loading liquid paint into reservoir for airless spray (potmen) Model: TNsG Model 6 PPE: no RPE, eye/face protection, gloves and single impermeable coverall (Tier 2a)	Total systemic exposure: 0.038 mg/kg bw /day MOE : 474
Application: Airless spraying viscous solvent-based liquids at > 100 bar, overhead and forwards (sprayers, covers also ancillary workers) Model: TNsG Model 3 PPE: RPE (APF 10), eye/face protection, gloves and impermeable coverall (Tier 2a)	Total systemic exposure: 0.043 mg/kg bw /day MOE : 420
Application: Brush and roller application (cleaning of a brush added) Model: Consumer product Painting Model 4, revised by HEEG PPE: no RPE, eye/face protection, gloves (Tier 2a)	Time 90 min: Total systemic exposure: 0.068 mg/kg bw /day MOE : 265
Primary exposure - non-professional use	
Brush and roller application (cleaning of	Total systemic exposure: 0.150 mg/kg bw /day

a brush added) Model: Consumer product Painting Model 4, revised by HEEG No PPE (100% clothing penetration)	MOE : 167 MOE : 521
Paint removal - professionals hydroblasting or grit blasting of product initially containing 2.76% a.s. Model: HEEG Opinion on the paper by Links. et al 2007 PPE: RPE (APF 40), protective clothing	Total systemic exposure: 0.016 mg/kg bw /day MOE : 1125
Paint removal - non-professionals hydroblasting or grit blasting of product initially containing 2.76% a.s. Model: HEEG Opinion on the paper by Links. et al 2007 No PPE: (100% clothing penetration)	Total systemic exposure: 0.077 mg/kg bw /day MOE : 324
Secondary exposure	
Cleaning of working clothes	
Worst case, 135 min/application	Total systemic exposure: 0.0014 mg/kg bw /day MOE : 18000
Refinement, 90min/day application	Total systemic exposure: 0.00093 mg/kg bw /day MOE : 27000
Child touching a boat surface (acute)	A) 0.15 mg/kg bw /day MOE: 166 B) 0.22 mg/kg bw /day MOE: 114

The metabolite N,N-dimethylsulfamide

Acute toxicity

Rat LD_{50} oral	higher than 2000 mg/kg bw

Repeated dose toxicity

Species/ target / critical effect	Rat, subacute 28-day oral study. Focal/multifocal cortical/medullary mineralization of kidney
Lowest relevant oral NOAEL / LOAEL	It was not possible to determine a LOAEL or a NOAEL for the study with certainty. However, a precautionary approach could be taken in interpreting the results of this study from which a NOAEL of 200 mg/kg/d could be derived, based on agreement in TMI 08.

Genotoxicity	*In vitro* tests (Ames and HPTR): Negative

	results *In vivo* test (micronucleus test): The conclusion of TM I 08 was that the result is negative.

Other toxicological studies

A QSAR analysis: DEREK for Windows, Program version DfW_9.0.0	No structural alerts found

Summary	Value	Study	Safety factor
Non-professional user			
ADI (acceptable daily intake, external long-term reference dose)	not relevant		

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Tolylfluanid: pH___9___: DT_{50} (10°C) = 1.6 h DT_{50} (20°C) = 0.49 h DT_{50} (25°C) = 0.29 h
	Tolylfluanid: pH___7___: DT_{50} (10°C) = 161 h DT_{50} (20°C) = 40.0 h DT_{50} (25°C) = 20.5 h
	Tolylfluanid: pH___4___: DT_{50} (10°C) = 3980 h DT_{50} (20°C) = 961 h DT_{50} (25°C) = 490 h
	Hydrolysis in sea water pH___8.2___: DT50 (10°C) = 5.9 h DT50 (20°C) = 2.0 h DT50 (25°C) = 1.2 h
	DMST is hydrolytically stable. N,N-DMS is hydrolytically stable.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Tolylfluanid does not absorb any light at wavelengths above 290 nm. It is not degradable by direct photodegradation in water.
Readily biodegradable (yes/no)	No

Biodegradation in seawater	n.a.
Non-extractable residues	n.d.
Distribution in water / sediment systems (active substance)	DT50 of tolylfluanid (N-methyl-^{14}C-labelled) (20°C) was 0.2-0.3 days in water (dissipation) and in total system (degradation). Tolylfluanid was not detected in the sediment. Realistic worst case DT50= 0.3 days (20°C), 0.6 days (12°C) & 0.7 days (9°C)
Distribution in water / sediment systems (metabolites)	DT50 (dissipation) of DMST (20°C) was 15-23 days in water and 15-41 days in sediment, respectively. DT50 (degradation) in total system was 18-48 days; realistic worst case DT50= 23 days (20°C) DT50 (dissipation) of DMST-acid (20°C) was 3.5-28 days in water and 6.9-17 days in sediment. DT50 (degradation) in total system was 4.0-10 days; realistic worst case DT50= 28 days (20°C) DT50 (dissipation) of N,N-DMS (20°C) in water, sediment and total system was >1000 days; realistic worst case DT50> 1000 days (20°C) .

Route and rate of degradation in soil

Mineralization (aerobic)	33-44 % after 120 days (N-methyl-^{14}C-labelled tolylfluanid)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50} (20°C, aerobic): 0.29-0.8days (Tolylfluanid), geometric mean=0.59 days; realistic worst case DT50= 0.8 days (20°C) & 1.5 days 12°C DT_{50} (20°C, aerobic): 1.2-2.9 days (DMST), geometric mean=2.1 days; realistic worst case DT50= 2.9 days (20°C) & 5.5 days 12°C DT_{50} (20°C, aerobic): 1.1-2.2 days (DMST-acid, but never >10% of applied radioactivity), geometric mean=1.4 days DT_{50} (20°C, aerobic): 47-699 days (N,N-DMS), geometric mean=153 days; realistic worst case DT50= 699 days (20°C) & 1325 days 12°C
	DT_{90lab} (20°C, aerobic): - DT_{90lab} (20°C, aerobic):-
	DT_{50lab} (10°C, aerobic): -

	DT_{50lab} (10°C, aerobic): -
	DT_{50lab} (20°C, anaerobic): not determined.
	degradation in the saturated zone: not determined
Field studies (state location, range or median with number of measurements)	DT_{50f}: not determined.
	DT_{90f}: not determined.
Anaerobic degradation	n.a.
Soil photolysis	-
Non-extractable residues	38.1-45.1%
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	DMST: 0.5-71.2% N,N-DMS: 0.9-23.1 %
Soil accumulation and plateau concentration	-

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Tolylfluanid: Ka_{oc} = 2220, log Ka_{oc} = 3.346 (soil)
	DMST: Ka_{oc}=56-118 (soil) DMST: Ka_{oc}=57, log Ka_{oc}=1.76 (marine sediment), Ka_{oc}=94, log Ka_{oc} = 1.97 (fresh water sediment) The arithmetic mean K_{oc} for DMST is 76 derived from 4 K_{oc} values in soil test and 2 values in sediment test, where one of the sediments was marine sediment.
	N,N-DMS: showed no adsorption to soil, the determination of Koc and Kd values was not possible, Ka_{oc}=0 (in the risk assessment of N,N-DMS)

Fate and behaviour in air

Direct photolysis in air	n.a.
Quantum yield of direct photolysis	n.a.
Photo-oxidative degradation in air	The half-life of Tolylfluanid in air with AOPWIN version 1.91 version is **0.9 days (21.5 hours)** (24-hr day; 0.5E6OH/cm3) and the respective chemical lifetime 1.3 days.

	The half-life of DMST in air with AOPWIN version 1.91 version is **0.3 days (7 hours)** (24-hr day; 0.5E6OH/cm3) and the respective chemical lifetime 0.4 days. The DT50 in air of N,N-DMS was not calculated.
Volatilization	2 x 10^{-4} Pa at 20°C (extrapolated) (Tolylfluanid) 6.6 × 10^{-2} Pa· m³· mol^{-1} (Tolyfluanid) 2.5 x 10^{-4} Pa at 20°C (extrapolated) (DMST) 7.7 × 10^{-5} Pa· m³· mol^{-1} (DMST)

Monitoring data, if available

Soil (indicate location and type of study)	n.a.
Surface water (indicate location and type of study)	In the Dutch recreational lakes and marinas (2007-2008): N,N-DMS: 290-2250 ng/l, DMSA (degradation products of dichlofluanid): 17-1000 ng/l(Kleinnijenhuis & Puijker. 2008, Kleinnijenhuis 2008). In the Dutch untreated and treated raw water and drinking water (2007-2008): N.N-DMS > 0.1 µg/l in surface water intended for the abstraction of drinking water was detected (Kleinnijenhuis & Puijker. 2008, Kleinnijenhuis 2008). In Norway: screening study 2011-2012 in two lakes close to Oslo N,N-DMS:104-774 ng/l (Langfors 2012). In the Swedish screening program of 2007 SWECO Environment in different matrices Sweden: Tolylfluanid detecded only in the sediment of storm water manholes at a paint industry (0.26 and 0.85 mg/kg) and in soil (0.3 mg/kg) at a storage site for treated wood (Törneman et al. 2009).
Ground water (indicate location and type of study)	n.a.
Air (indicate location and type of study)	n.a.

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Rainbow trout *(Oncorhynchus mykiss*)	96 hours	Mortality, LC_{50}	0.016 mg/l (Tolylfluanid)
			=100 mg/l (N,N-DMS)
	28 days	Reproduction, NOEC	=100 mg/l (N,N-DMS)
Sheephead minnow (*Cyprinodon variegatus*)	96 hours	Mortality, LC_{50}	27.5 mg/l (DMST) marine
Pimephales promelas	33 days	Reproduction, NOEC	0.004 mg/l (Dichlofluanid)
	32 days	Fish ELS, NOEC	10 mg /l (DMST)
Invertebrates			
Daphnia magna	48 hours	Mortality, LC_{50}	0.19 mg/l (Tolylfluanid)
			=100 mg/l (N,N-DMS)
	21 days	Reproduction, NOEC	0.00265 mg/l (Dichlofluanid)
			=100 mg/l (N,N-DMS)
			5.6 mg/l (DMST)
Mysidopsis bahia	48 hours	Mortality, LC_{50}	21.5 mg/l (DMST)
Midge *(Chironomus riparius)*	28 days	Development rate female, EC_5=NOEC	1.4 mg/l (DMST)
Leptocheirus plumulosus	10 days	Mortality, LC_{50}	74 mg/kg dw (DMST)
Algae			
Green alga (*Selenastrum capricornutum*)	72 hours	Growth inhibition, NOE_rC, E_rC_{50}	Tolylfluanid: NOErC=0.040 mg/l $ErC_{50=}$0.4 mg/l
Navicula pelliculosa	72 hours	Growth inhibition, NOE_rC, E_rC_{50}	DMST: NOErC=12.3 mg/l ErC_{50}=46 mg/l
Pseudokirchnerella subcapitata	72 hours	Growth inhibition NOErC,ErC_{50}	N,N-DMS: NOErC=100 mg/l ErC_{50}>100 mg/l
Aquatic plants			

Lemna gibba	14 days	Growth inhibition IC_{50}	72.1 mg/l (DMST)
Microorganisms			
Activated sludge (mixed population)	3 hours	Oxygen consumption	Tolylfluanid: EC_{50}=230 mg/l, EC_{10}=21, Conclusion: NOEC>solubility of tolylfluanid, i.e.1.0 mg/l
			DMST: EC_{10}= 143 mg/l

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworm (*Eisenia fetida*)	LC_{50} (14 days) > 78.5 mg/kg ww (Tolylfluanid)
Reproductive toxicity to Earthworm *(Eisenia fetida*	NOEC (56 days) = 3.8 mg /kg ww (Tolylfluanid)
	NOEC (56 days) = 9.8 mg/kg ww (DMST)
	NOEC (56 days) = 108 mg/kg ww (N,N-DMS)
Reproductive toxicity to Springtail *(Folsomia candida)*	NOEC (28 days) = 95 mg/kg ww (N,N-DMS)
Acute toxicity to terrestrial plants	Oat, onion, sugar beet, turnip, carrot, soybean: EC_{50} TWA 21 days (seedling emergence) > 2.4 mg/kg ww

Effects on soil micro-organisms

Nitrogen mineralization	NOEC (28 days) =3.3 mg/kg ww (Tolylfluanid)
	NOEC (28 days) =14.18 mg/kg ww (DMST)
	NOEC (28 days) = 15.24 mg/kg ww (N,N-DMS)
Carbon mineralization	NOEC (28 days)=3.0 mg/kg ww (Tolylfluanid)

DMST-acid: Ecotoxicity data was not available for DMST-acid, but a read across from DMST toxicity data has been done. (Q)SAR predictions carried out for DMST-acid support read across from DMST ecotoxity data. DMST and DMST-acid have closely related molecular structures, DMST-acid is more hydrophilic and has a lower bioconcentration potential compared to DMST.

Effects on terrestrial vertebrates

Acute toxicity to mammals	n.a.
Acute toxicity to birds	n.a.
Dietary toxicity to birds	n.a.
Reproductive toxicity to birds	n.a.

Effects on honeybees

Acute oral toxicity	n.a.
Acute contact toxicity	n.a.

Effects on other beneficial arthropods

Acute oral toxicity	n.a.
Acute contact toxicity	n.a.
Acute toxicity to	n.a.

Bioconcentration

Bioconcentration factor (BCF)	Tolylfluanid (l/kg ww): edible: 55, whole fish: 74
Depuration time (DT_{50}) (DT_{90})	Tolylfluanid: DT50 [days]: edible: 0.29, whole fish: 0.38
Level of metabolites (%) in organisms accounting for > 10 % of residues	

Appendix II: List of Intended Uses

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Rem.
(a)			(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	number min max (k)	interval between applications (min)	g as/L min max	water L/m^2 min max	g as/m^2 min max	(m)
PT21 to protect the underwater hull of commercial and pleasure craft	EU	Interspeed Ultra	Fouling organisms (e.g. alga, bacteria, barnacles)	Hard durable AF paint	Tolylfluanid: 2.76%ww Cu_2O: 44.35%ww	Airless spray/brush/roller	2 coats	24months	Theoretical application rates of the product: Airless spray: 3.0 m^2/l; 125 μm dry film thickness Brush/roller: 10.5m^2/l; 125 μm dry film thickness			Accepted data

*(a)e.g.*biting and suckling insects, fungi, molds; (b) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR),(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4); (d) All abbreviations used must be explained, (e) g/kg or g/l;(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench;(g) Kind, *e.g.* overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated; (h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions.

Appendix III. List of References

Section No in Doc III-A / Non-key study / Published	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
	Bayer CropScience AG	2003	Tolylfluanid - Dossier according to Directive 91/414/EEC - Annex IIA, Point 1-.	-	-	No	No	Yes	Bayer Crop Science AG
-	Fliege, S., Hartmann, K., Klamroth, E	2007	Tolylfluanid - Assessment of the relevance of the soil and ground water metabolite N,N-Dimethylsulfamide according to the "Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC (Sanco/221/2000)".	Bayer AG	. MEF-07/236	No	No	Yes	LANXESS Deutschland GmbH

Section No in Doc III-A / Non-key study / Published	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3 A8	Bayer Chemicals AG	2003a	Preventol A5-S, Safety Data Sheet.	-	SDS No. 861298 /08	No	Yes	No	LANXESS Deutschland GmbH
A3	Gueldner, W.	2001	Characterisation of the GSD- and MMAD-values of particle size distribution of Euparen M tech (AR 00284 122).	Bayer AG	14 1050 5186	Yes	No	Yes	LANXESS Deutschland GmbH
A3	Heinz, U.	2005	Determination of Safety-Relevant data of Tolylfluanid tech.	Bayer Industry Services GmbH & Co. OHG	05/007 52	Yes	No	Yes	LANXESS Deutschland GmbH
A3	Krohn, J.	1995b	Dissociation constant of Tolylfluanid.	Bayer AG	PC 1100	No	No	Yes	LANXESS Deutschland GmbH
A3 (3.1, 3.4, 3.5)	Schneider, J.	2002	Density, Water solubility and pKa Value in Dependence on Temperature of KUE13183B (Tolylfluanid).	Bayer Crop Science AG	140032 1075	Yes	No	Yes	LANXESS Deutschland GmbH

Section No in Doc III-A / Non-key study / Published	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.1	Krohn, J.	1994a	Melting point of Tolylfluanid.	Bayer AG	PC 578	No	No	Yes	LANXESS Deutschland GmbH
A3.1	Krohn, J.	1999	Density and vapour pressure of Tolylfluanid-DMST.	Bayer AG	146600 958	No	No	Yes	LANXESS Deutschland GmbH
A3.1	Weber, R.	1984	Tolylfluanid – Determination of density with an air comparison pycnometer (as described in 79/831/EC).	Bayer AG	PC 805	Yes	No	Yes	LANXESS Deutschland GmbH
A3.2	Bogdoll, B.; Lemke, G.; Kaussman n, M	2007a	Henry´s Law Constant of N,N-dimethylsulfamide	Bayer Ag	AF07/01 0		No	Yes	LANXESS Deutschland GmbH
A3.2	Krohn, J.	1993	Calculation of the Henry law constant of Tolylfluanid.	Bayer AG	PC 807	No	No	Yes	LANXESS Deutschland GmbH

Section No in Doc III-A / Non-key study / Published	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.2	Smeykal, H.	2007	N,N-dimethylsulfamide - Product code: BCS-AA10391 - Vapour pressure A.4. (OECD 104).	Siemens AG, Frankfurt am Main, Germany, Bayer CropScience 20070048.01, Edition Number: M-283855-01-1, unpublished, date: 2007-02-15.	-	-	No	yes	LANXESS Deutschland GmbH
A3.2	Weber, R.; Krohn, J.	1995	Vapour pressure curve of Tolylfluanid.	Bayer AG	PC 1101	No	No	Yes	LANXESS Deutschland GmbH
A3.3	Schneider, K.	2002a	Euparen M techn. (Tolylfluanid). Appearance.	Bayer AG	-	No	No	Yes	LANXESS Deutschland GmbH

Section No in Doc III-A / Non-key study / Published	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.3	Schneider, K.	2002b	Euparen M techn. (Tolylfluanid). Odour.	Bayer AG	-	No	No	Yes	LANXESS Deutschland GmbH
A3.4	Krohn, J.	1994b	Spectra of Tolylfluanid – Spectra of the active ingredient of Methyl-Euparen (Euparen M).	Bayer AG	PC 814	No	No	Yes	LANXESS Deutschland GmbH
A3.5	Eyrich, U.; Bogdoll, B	2007a	Water solubility of N,N-dimethylsulfamide at pH 5, pH 7 and pH 9 (Flask Method).	Bayer AG		Yes	No	Yes	LANXESS Deutschland GmbH
A3.5	Krohn, J.	1995a	Water solubility of Tolylfluanid.	Bayer AG	PC 1099	No	No	Yes	LANXESS Deutschland GmbH
A3.5	Malcharek, F.	1996	Water solubility. (DMST)	Bayer AG	A93/01 36/02 DOR	Yes	No	Yes	LANXESS Deutschland GmbH
A3.6	Bogdoll, B.; Lemke, G.; Kaussman n, M	2007b	N,N-dimethylsulfamide - Determination of the dissociation constant (Titration Screening Method).	Bayer AG	AF07/01 7, Edition Number : M-284258 -01-1		No	Yes	LANXESS Deutschland GmbH

Section No in Doc III-A / Non-key study / Published	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.6	Krohn, J.	1988	Partition coefficient – Tolylfluanid (Methyl-Euparen).	Bayer AG	5/0258 (PC 812)	No	No	Yes	LANXESS Deutschland GmbH
A3.6	Krohn, J.	1989	Octanol/water partition coefficient for Dimethylsulftoluidide (DMST).	Bayer AG	Q 5050412	No	No	Yes	LANXESS Deutschland GmbH
A3.7	Krohn, J.	1996	Solubility of Tolylfluanid in representative organic solvents.	Bayer AG	PC 1118	Yes	No	Yes	LANXESS Deutschland GmbH
A3.7	Mix, K.H.; Berg, G.	1988	Thermal stability of the active ingredient Tolylfluanid (KUE 13183 B).	Bayer AG	PC 816	No	No	Yes	LANXESS Deutschland GmbH
A3.8	Mix, K.H.	1996	Determination of the safety-relevant parameters of Euparen M.	Bayer AG	PC 1245	No	No	Yes	LANXESS Deutschland GmbH

Section No in Doc III-A / Non-key study / Published	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.9	Eyrich, U.; Bogdoll, B	2007 b	Partition coefficients 1-octanol / water of N,N-dimethylsulfamide at pH 5, pH 7 and pH 9 (Shake Flask Method)	Bayer AG		Yes	No	Yes	LANXESS Deutschland GmbH
A3.10	Krohn, J.	1995c	Surface tension of Tolylfluanid.	Bayer AG	PC1116	Yes	No	Yes	LANXESS Deutschland GmbH
A3.12	Schneider, K.	2002c	Euparen M techn. (Tolylfluanid) – Oxidizing properties.	Bayer AG	-	No	No	Yes	LANXESS Deutschland GmbH
A3.13	Seidel, E.	2000	Corrosion Characteristics of Tolylfluanid techn. Accelerated Test.	Bayer AG	141905 1007	Yes	No	Yes	LANXESS Deutschland GmbH
A4.1	Hake, G.	2004a	Tolylfluanid (KUE13183B) Assay of Technical Grade Active Ingredient HPLC – External Standard.	Bayer CropScience AG	AM002004MP1	No	No	Yes	LANXESS Deutschland GmbH

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A4.1	Hake, G.	2004b	Validation of HPLC-method AM002004MP1 KUE 13183B Assay of Technical - Grade Active Ingredient.	Bayer CropScience AG	VB1-AM002004MP1	No	No	Yes	LANXESS Deutschland GmbH
A4.2	Brenneke, R.	1991	Residue analytical method, modification recoveries.	Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany	Az. 00086/M014	No	No	Yes	LANXESS Deutschland GmbH
A4.2	Brumhard, B.	2004	Analytical method 00904 for the determination of tolylfluanid and DMST in drinking and surface water by HPLC-MS/MS.	Bayer CropScience AG	MR-132/04	Yes	No	Yes	LANXESS Deutschland GmbH
A4.2	Hahn, J.A.	2003	Validation of an analytical method for the determination of residues of tolylfluanid and DMST in synthetic seawater.	ABC Laboratories Inc., USA	46586-1	Yes	No	Yes	LANXESS Deutschland GmbH

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A4.2	Hellpointner, E.	2001	Confirmatory method for the determination of Tolylfluanid in air (confirmed method 00292).	Bayer AG	00292C	Yes	No	Yes	LANXESS Deutschland GmbH
A4.2	Lakaschus, S.	2004a	Enforcement method for the determination of residues of tolylfluanid in materials of soil – validation of DFG method S 19 (extended and revised version) (Bayer CropScience Method 00086/M064)	Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany	G04-0007	Yes	No	Yes	LANXESS Deutschland GmbH
A4.2	Lakaschus, S.	2004b	Validation of enforcement method DFG S 19 (extended and revised version) (Bayer CropScience Method 00086/M065) for the determination of residues of DMST in soil.	Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany	G04-0082	Yes	No	Yes	LANXESS Deutschland GmbH

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A4.2	Riegner, K.	1992	Method for the determination of Tolylfluanid in air.	Bayer AG	0092	Yes	No	Yes	LANXESS Deutschland GmbH
A4.2	Specht, W.; Thier, H.-P.	1989	Organochlorine and organophosphorus compounds as well as nitrogen containing and other plant protectans – Gas chromatographic determination after clean-up by gel permeation chromatography and ata mini-silica gel column. DFG method S 19.	Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany	00086	No	No	Yes	LANXESS Deutschland GmbH

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A4.2	Specht, W.; Pelz, S.; Gilsbach, W.	1995	Modified extraction: Gas-chromatographic determination of pesticide residues after clean-up by gel-permeation chromatography and mini-silica gel-column chromatography - 6. Communication: Replacement of dichloromethane by ethyl acetate.	Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany	MO-01-012505 Fresenius J Anal Chem 353 (1995) p. 183.	No	No	Yes	LANXESS Deutschland GmbH
A4.2	Veith, M.	1999	Validation-report VB1.2-2201-0192503-97E.	Bayer AG	VB1.2-2201-0192503	No	No	Yes	LANXESS Deutschland GmbH
A4.2	Weber, H.	2001a	Enforcement method 00561/M001 for the determination of residues of Tolylfluanid in blood by GC-MS.	Dr. Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany	00561/M001	Yes	No	Yes	LANXESS Deutschland GmbH

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A4.2	Weeren, R.D.	1998	Determination of Tolylfluanid in soil.	Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany	Report attachment in "Brennecke 1991"	No	No	Yes	LANXESS Deutschland GmbH
A4.2	Weeren, R.D. and Schmidt, F	1996	Independent laboratory validation (ILV) of Bayer method 00435 for the determination of the residues of tolylfluanid in matrices of animal origin	Dr. Specht & Partner Chemische Laboratorien GmbH, Germany	BAY-9602V	No	No	Yes	LANXESS Deutschland GmbH
A4.2	Weeren, R.D. Pelz, S.	1999	Validation of an analytical method (analogous to DFG method W 5) for the determinaton of residues of Tolylfluanid and Dimethylsulfotoluidid (DMST) in drinking and surface water.	Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany	00054/E002	Yes	No	Yes	LANXESS Deutschland GmbH

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A4.2.3	Krebber,R.	2008	AMENDMENT NO. 1 TO REPORT NO. MR-07/242. Method 01041 for the determination of N,N-dimethylsulfamide in water by HPLC-MS/MS.	Bayer CropScience AG	Report No. MR-07/242	No	No	Yes	LANXESS Deutschland GmbH
A4.2.3	Krebber,R& Braune, M	2007	Method 01041 for the determination of N,N-dimethylsulfamide in water by HPLC-MS/MS.	Bayer CropScience AG	MR-07/242	No	No	Yes	LANXESS Deutschland GmbH
A4.2e (3)	Maasfeld, W.	1996	method for the determination of residues of tolylfluanid in foodstuffs of animal origin (validation), Bayer method-no. 00435,	Bayer AG,	MR-272/96		No	Yes	LANXESS Deutschland GmbH
A5.2.1	Kugler, M.	2003	Test Report: Determination of the antimicrobial effects of Preventol A 5-S against bacteria and fungi.	Bayer Chemicals AG	2003-04-14	No	No	Yes	LANXESS Deutschland GmbH

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A5.2.1	Overbeke, J.C.; Klijnstra, J.W.	2004a	Investigation of antifouling performance of menthol derivates in experimental paints.	TNO, The Netherlands	CA04.5091	No	No	Yes	LANXESS Deutschland GmbH
A5.2.1	Overbeke, J.C.; Klijnstra, J.W.	2004b	Investigation of antifouling performance of three experimental paints.	TNO, The Netherlands	CA04.5092	No	No	Yes	LANXESS Deutschland GmbH
A5.3.1	Klijnstra, J.W.; Bos, T.	1999	Influence of 10 chemical compounds on barnacle settlement behaviour.	TNO, The Netherlands	007.40200/00.03	No	No	Yes	LANXESS Deutschland GmbH
A5.3.1	Klijnstra, J.W.; Head, R.M.	2001 (amend. 2006)	Antifouling Efficacy of Dichlofluanid.	TNO, The Netherlands	CA01.9036	No	No	Yes	LANXESS Deutschland GmbH
A6	[redacted]	2007	KUE 13183B-N,N-dimethylsulfamid – 28-day toxicity study in the rat by oral administration.	[redacted]	-	No	No	yes	LANXESS Deutschland GmbH

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A6	[redacted]	2007	KUE 13183B-N,N-dimethylsulfamid (Project: Tolylfluanid (KUE 13183B)) - Acute toxicity in the rat after oral administration.	[redacted]	AT0367 5,	Yes	No	Yyes	LANXESS Deutschland GmbH
A6.01.3-	[redacted]	2007	On the investigation of two material samples labelled "Tolylfluanid [redacted]" and Tolylfluanid [redacted]" to examine the dustiness behaviour via measurements of respirable, thoracic and inhalable dust values according to DIN 33897, part 2, "Continuous drop in counter current" and EN 15051, Method B, "Continuous drop"	[redacted]	A 6357/0 7, 2006-02-06-	Yes-	No-	Yes-	LANXESS Deutschland GmbH

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A6.1.1	[redacted]	1995a	KUE 13183B (c.n.: Tolylfluanide) - Study for acute oral toxicity in rats.	[redacted]	23615	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.1	[redacted]	1978	Triadimefon and Tolylfluanid - Study for acute combination toxicity.	[redacted]	7304	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.1	[redacted]	1983	KUE 13183 b (Tolylfluanid, Euparen M active ingredient) - Study for acute toxicity.	[redacted]	11383	No	No	Yes	LANXESS Deutschland GmbH
A6.1.1	[redacted]	1967	KUE 13183 B - Toxicological studies on the active ingredient BAY 49854.	[redacted]	323	No	No	Yes	LANXESS Deutschland GmbH
A6.1.1	[redacted]	1971	Methyl-Euparen - Subacute cutaneous application to rabbits.	[redacted]	2619	No	No	Yes	LANXESS Deutschland GmbH

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A6.1.2	[redacted]	1995b	KUE 13183B (c.n.: Tolylfluanide) - Study for acute dermal toxicity in rats.	[redacted]	23616	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.3	[redacted]	1997	KUE 13183 B (Common name: Tolylfluanid) – Study on acute inhalation toxicity in rats according to OECD No. 403.	[redacted]	26653	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.3	[redacted]	1999	PREVENTOL A 9-D (c.n.: Tolylfluanid) – Study on acute inhalation toxicity in rats according to OECD No. 403.	[redacted]	28976	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.3	[redacted]	2001	KUE 13183 B (common name: Tolylfluanid) – Study on acute inhalation toxicity in rats according to OECD no. 403.	[redacted]	30639	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.1.3	[redacted]	2002b	KUE 13183 B (Common name: Tolylfluanid) Analysis of bronchoalveolar-lavage following acute inhalation toxicity in rats (Exposure: 1 × 4 hours).	[redacted]	AT00006	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.3	[redacted]	2002c	KUE 13183 B (Common name: Tolylfluanid) Upper respiratory tract sensory irritation in mice and rats.	[redacted]	AT00001	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.3	[redacted]	2002d	KUE 13183 B (Common name: Tolylfluanid) Analysis of bronchoalveolar-lavage following acute inhalation toxicity in rats (Exposure: 1 × 4 hours).	[redacted]	32300	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.1.4	[redacted]	1994 (amend. 2000)	KUE 13183 B (c. n.: tolylfluanid) – Study for skin and eye irritation/corrosion in rabbits.	[redacted]	22860	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.4	[redacted]	1984	KUE 13183 b (Euparen M active ingredient) (c.n. tolylfluanid) – Study for irritant/corrosive effect on skin and eye (rabbit).	[redacted]	12362	No	No	Yes	LANXESS Deutschland GmbH
A6.1.5	[redacted]	1990	KUE 13183B (c.n. Tolylfluanid) - Study for skin sensitizing effect on guinea pigs (Buehler's Patch test).	[redacted]	18630	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.5	[redacted]	1991	KUE 13183 B - Study for skin-sensitizing effects on guinea pigs (Klecak Open Epicutaneous test).	[redacted]	19981	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.1.5	[redacted]	1983	KUE 13183 B - Study for sensitising effect on guinea pigs.	[redacted]	11492	No	No	Yes	LANXESS Deutschland GmbH
A6.1.5	[redacted]	1975	Euparen M 50% WP - Absorption test on the skin of rabbits.	[redacted]	5573	No	No	Yes	LANXESS Deutschland GmbH
A6.2	[redacted]	1988 (amend. 2000)	Investigation of the biokinetic behaviour in the rat.	[redacted]	PF2989	Yes	No	Yes	LANXESS Deutschland GmbH
A6.2	[redacted]	1978	Biotransformation of [^{14}C] Tolylfluanid in the rat.	[redacted]	PF1282	Yes	No	Yes	LANXESS Deutschland GmbH
A6.2	[redacted]	1987 (amend. 2000)	Biotransformation of [ring-U-14C] tolylfluanid by the rat following oral administration.	[redacted]	PF2826	Yes	No	Yes	LANXESS Deutschland GmbH
A6.2	[redacted]	1995	[Phenyl-U-14C] Tolylfluanid absorption, distribution, excretion and metabolism in a lactating goat.	[redacted]	PF4106	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.2	[redacted]	1991 (amend. 2000)	[U-Phenyl-14C] tolylfluanid: General rat metabolism study.	[redacted]	PF3785	Yes	No	Yes	LANXESS Deutschland GmbH
A6.2	[redacted]	2001	In vitro percutaneous absorption study with Phenyl-UL-14C]Tolylfluanid (Euparen M 50 WG) using human and rat epidermal membranes.	[redacted]	V 3263	Yes	No	Yes	LANXESS Deutschland GmbH
A6.2	[redacted]	1988 (amend. 2000)	[Phenyl-UL-14C] tolylfluanid: Whole-body autoradiographic distribution of the radioactivity in the rat.	[redacted]	PF2961	Yes	No	Yes	LANXESS Deutschland GmbH
A6.2	[redacted]	2001b	[Phenyl-UL-14C]Tolylfluanid 50 WG (Euparen M) - Percutaneous absorption study in the rat.	[redacted]	MR 130/01	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.2	[redacted]	1977	Tolylfluanid-14C (Euparen M active substance) Biokinetic investigations of rats.	[redacted]	PF1165	Yes	No	Yes	LANXESS Deutschland GmbH
A6.3	[redacted]	1988	KUE 13183 b - Subacute toxicological study on the question of an effect on the thyroid in rats (four-week feeding test).	[redacted]	17183	Yes	No	Yes	LANXESS Deutschland GmbH
A6.3	[redacted]	1995	KUE 13183 B - Subacute dermal toxicity study on rabbits.	[redacted]	23712	Yes	No	Yes	LANXESS Deutschland GmbH
A6.3	[redacted]	1996a	KUE 13183B (Common name: Tolylfluanid) – Study on acute inhalation toxicity in rats according to OECD No. 403.	[redacted]	25503	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.3	[redacted]	1996b	KUE 13183B (common name: Tolylfluanid) – Pilot-Study on subacute inhalation toxicity in rats (5x6 hours exposition).	[redacted]	25437	Yes	No	Yes	LANXESS Deutschland GmbH
A6.3	[redacted]	1997	KUE 13183B (common name: Tolylfluanid) – Study on subacute inhalation toxicity in rats (20 × 6 hours exposure) according to OECD-Guideline no. 412.	[redacted]	25828	Yes	No	Yes	LANXESS Deutschland GmbH
A6.3	[redacted]	2002a	KUE 13183 B Subacute inhalation toxicity on rats (Exposure 20 × 6 hour/day for 4 weeks).	[redacted]	31791	Yes	No	Yes	LANXESS Deutschland GmbH
A6.4	[redacted]	1976	KUE 13183B - Subchronic toxicological experiments on rats (feeding experiment over 3 months).	[redacted]	5929	No	No	Yes	LANXESS Deutschland GmbH

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A6.4	[redacted]	1995a (amend. 2000)	KUE 13183B (common name: Tolylfluanid) - Subchronic toxicity study in Wistar rats (thirteen-week administration in the diet with a four-week recovery period).	[redacted]	24334	Yes	No	Yes	LANXESS Deutschland GmbH
A6.4	Heimann, K.G.	2003	Tolylfluanid – Waiver for a subchronic dermal study.	Bayer CropScience AG	MO-03-012002	No	No	Yes	LANXESS Deutschland GmbH
A6.4	[redacted]	1974	KUE 13183 b (tolylfluanide, Euparen M) - Subchronic toxicity study on dogs (thirteen-week feeding experiment).	[redacted]	4957	No	No	Yes	LANXESS Deutschland GmbH
A6.5	[redacted]	1986	KUE 13183b (Tolylfluanid) - Chronic toxicity to dogs after oral administration (12-month capsule study).	[redacted]	12999	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.5	[redacted]	1982	KUE 13183 b (Tolylfluanid, Euparen M active ingredient) – Chronic toxicological study in rats (feeding for two years).	[redacted]	10978	No	No	Yes	LANXESS Deutschland GmbH
A6.5	[redacted]	1996 (amend. 2000)	KUE 13183b (c.n. Tolylfluanid) – Study on Chronic Toxicity and Carcinogenicity in Wistar rats (administration in food over 2 years).	[redacted]	25426	Yes	No	Yes	LANXESS Deutschland GmbH
A6.5	[redacted]	1996 (amend. 2000)	KUE 13183b (c.n. Tolylfluanid) – Oncogenicity study in B6C3F1 mice (administration in food over 2 years).	[redacted]	25548	Yes	No	Yes	LANXESS Deutschland GmbH
A6.5	[redacted]	1982	KUE 13183 b – Study for cancerogenic effect on NMRI mice (feeding study for 104 weeks).	[redacted]	R2225	No	No	Yes	LANXESS Deutschland GmbH

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A6.5	[redacted]	1997 (amend. 2000)	KUE 13183 b (c.n. Tolylfluanid) - Chronic (52 week) oral toxicity study in dogs.	[redacted]	26664	No	No	Yes	LANXESS Deutschland GmbH
A6.6	[redacted]	1987	Mutagenicity test on KUE 13183b in the CHO/HGPRT forward mutation assay.	[redacted]	R4204	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6	[redacted]	1997	^{32}P-postlabeling assay for detection of adduct formation by tolylfluanid (TF) in rat lung, thyroid and liver DNA.	[redacted]	R6933	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.1	[redacted]	1995	Tolylfluanid (KUE 13183 b) - In vitro characterization of the properties of its metabolite 2-thiazolidinethione-4-carboxylic acid (TTCA).	[redacted]	24435	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.6.1	Herbold, B.	1979	KUE 13183b - Salmonella/microsome test for point mutagenic effects.	Bayer AG	8265	No	No	Yes	LANXESS Deutschland GmbH
A6.6.1	Herbold, B.	1994	KUE 13183b - Salmonella/microsome test.	Bayer AG	22843	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.1	Hoorn, A.J.W.	1984	Mutagenicity evaluation of KUE 13 183b (c.n. Tolylfluanid) in the reverse mutation induction assay with Saccharomyces cerevisiae strains S 138 and S 211.	Litton Bionetics, The Netherlands	R3060	(Yes)	No	Yes	LANXESS Deutschland GmbH
A6.6.1	Narumi, K.	2004	Chromosomal Aberration Study of Prevented A5-S in Cultured Mammalian Cells.	Kashima Laboratory, Mitsubishi Chemical Safety Institute Ltd., Japan	B040330	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.6.2	Herbold, B.	1984a (amend. 2000)	KUE 13183b (c.n. tolylfluanid) - Cytogenetic study with human lymphocyte cultures in vitro to evaluate for harmful effect on chromosomes.	Bayer AG	12836	(Yes)	No	Yes	LANXESS Deutschland GmbH
A6.6.2	Herbold, B.	1996	KUE 13183b - In vitro mammalian chromosome aberration test with chinese hamster V79 cells.	Bayer AG	24581	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.2	Hoorn, A.J.W.G.; Heidemann, A.	1985	Mutagenicity evalulation of KUE 13183B (c.n. Tolylfluanid) in the mouse lymphoma forward mutation assay.	Litton Bionetics, The Netherlands	R3192	(Yes)	No	Yes	LANXESS Deutschland GmbH

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A6.6.3	Brendler-Schwaab, S.	1995	KUE 13183B - Test on unscheduled DNA synthesis in rat liver primary cell cultures in vitro.	Bayer AG	24436	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.3	Heidemann, A.; Miltenburger, H.G.	1987	KUE 13183b - Detection of gene mutations in somatic mammalian cells in culture: HGPRT-test with V79 cells - Test report of study LMP 260.	Laboratorium für Mutagenizitätsprüfung, Germany	R4103	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.3	[redacted]	1990	Chromosome aberration assay in bone marrow cells of the chinese hamster with KUE 13183b.	[redacted]	R5153	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.4	[redacted]	1980	KUE 13183 b (Tolylfluanid) - Micronucleus test on the mouse to evaluate for mutagenic effect.	[redacted]	9149	No	No	Yes	LANXESS Deutschland GmbH

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A6.6.4	[redacted]	1983 (amend. 2000)	KUE 13183 b (Tolylfluanid, Euparen M, Preventol VP OC 3017) - Cytogenetic study of the Chinese hamsters bone marrow in vivo to evaluate for mutagenic effect	[redacted]	11792	(Yes)	No	Yes	LANXESS Deutschland GmbH
A6.6.4	[redacted]	2004	KUE 13183B – In Vivo Bone Marrow Cytogenetic Study Using Male Mice.	[redacted]	AT01134	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.4	[redacted]	1988a	Sister chromatid exchange assay in bone marrow cells of the mouse with KUE 13183B.	[redacted]	R4422	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.5	[redacted]	1984b	KUE 13183b - Cytogenetic study of the spermatogonia of the chinese hamster in vivo to evaluate for mutagenic effect.	[redacted]	12739	No	No	Yes	LANXESS Deutschland GmbH

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A6.6.5	[redacted]	1986	KUE 13183b c. n. tolylfluanid - Dominant lethal test on the male mouse to evaluate for mutagenic effect.	[redacted]	15017	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.5	[redacted]	1988	KUE 13183b (c.n. tolylfluanid) - Spot test on cross-bred C57B1/6J × T stock mouse fetuses to evaluate for induced somatic changes in the genes of the coat pigment cells.	[redacted]	16752	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.6	[redacted]	1988b	Mouse germ-cell cytogenetic assay with KUE 13 183b.	[redacted]	R4485	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.8.1	[redacted]	1995 (amend. 2000)	A developmental toxicity study with orally administered KUE 13183b technical in the rat.	[redacted]	MTD9405	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.1	[redacted]	1991b (amend. 2000)	KUE 13183B (common name: Tolylfluanid) - Study for embryotoxic effects on rabbits following oral administration.	[redacted]	20034	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.1	[redacted]	1991c	KUE 13183B (common name: Tolylfluanid) - Supplementary study for maternal toxicity to gravid rabbits following oral administration.	[redacted]	19901	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.1	[redacted]	1976	Product KUE 13183 b – Studies of embryotoxic and teratogenic effects on rats after oral administration.	[redacted]	5888	No	No	Yes	LANXESS Deutschland GmbH

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A6.8.2	[redacted]	1991a (amend. 1995)	KUE 13183 b (c.n. Tolylfluanid) - Two-generation study on rats (supplement to study T1007392).	[redacted]	20583	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.2	[redacted]	1989	KUE 13183 b (c.n. Tolylfluanide) – Two-generation study on rats.	[redacted]	17788	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.2	[redacted]	1980	KUE 13183b (Euparen M-active ingredient) – Two-generation study with rats.	[redacted]	9419	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.2	[redacted]	1995 (amend. 2000)	KUE 13183 B – Two-generation study in rats.	[redacted]	23921	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.2	[redacted]	2004	Supplemental Submission to Bayer CropScience LP Report No. 200770.	[redacted]	200770-1	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.8.2	[redacted]	2004	KUE 13183 (Tolylfluanid): A Two-Generation Reproductive Toxicity Study in the Wistar Rat.	[redacted]	200770	Yes	No	Yes	LANXESS Deutschland GmbH
A6.9	[redacted]	1995b (amend. 2000)	KUE 13183B (common name: Tolyfluanid) - Subchronic neurotoxicity screening study in Wistar rats (thirteen-week administration in the diet).	[redacted]	24336	Yes	No	Yes	LANXESS Deutschland GmbH
A6.9	[redacted]	1994	KUE 13183B (common name: Tolylfluanid) - Acute oral neurotoxicity screening studies in rats.	[redacted]	23517	Yes	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Andersson, L. (Bayer Sverige AB, Norway)	1994	Euparen M / Tolylfluanid.	-	LETTER (MO-00-002460)	No	No	Yes	LANXESS Deutschland GmbH

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A6.12.1	Bayer B.V., The Netherlands	1993d	Euparen M / Tolylfluanid.	-	LETTER (MO-00-002467)	No	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Bayer S.A., Belgium	1993c	Euparen M / Tolylfluanid.	-	LETTER (MO-00-002481)	No	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Bayer S.P.A., Italy	1993b	Preventol A 5.	-	LETTER (MO-00-002485)	No	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Faul, J.	1982	Statement to Pkt IV/1.2.2. of the BBA application 'details of effects on man, internal company experience'.	Bayer AG	MO-99-014598	No	No	Yes	LANXESS Deutschland GmbH

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A6.12.1	Faul, J.	1989	Euparen und Euparen M - In-company occupational medical experience.	Bayer AG	MO-99-014594	No	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Faul, J.	1993	Preventol A5 (Tolylfluanid) / Werksärztliche Stellungnahme.	Bayer AG	MO-99-014087	Yes	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Imsgard, F.	1993	Overview concerning the use of Preventol A5 (Tolylfluanide) by GORI, DK-6000 Kolding.	-	LETTER (MO-00-002498)	No	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Kehrig, B.	2001	Experience of the company occupational health service with tolylfluanid (methyl-Euparen).	Bayer AG	MO-01-011204	No	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Nathan, U. (Bayer AS, Denmark)	1994	Euparen-M.	-	LETTER (MO-00-002466)	No	No	Yes	LANXESS Deutschland GmbH

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A6.12.1	Olloz, F. (Pentol AG, Switzerland)	1993	Preventol A5 / Tolylfluanide – Data on experience with Preventol A5.	-	LETTER (MO-00-002504)	No	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Roos, B. (Geveko Oy, Finland)	1993	Tolylfluanid VP OC 3049.	-	LETTER (MO-00-002495)	No	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Schneeberger, R. (Blaser + Co. AG, Switzerland)	1993	Tolylfluanide – Report on experience with its use.	-	LETTER (MO-00-002500)	Yes	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Sturm, K. (Bayer S.A., France)	1993	Euparen M.	-	LETTER (MO-00-002483)	No	No	Yes	LANXESS Deutschland GmbH
A6.12.1	Wolff, M.	1994	Tolylfluanid.	Bayer AG	MO-99-014089	No	No	Yes	LANXESS Deutschland GmbH

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A6.12.1	Zetagi, C. (Bayer S.P.A., Italy)	1993	Preventol A 5.	-	LETTER (MO-00-002494)	No	No	Yes	LANXESS Deutschland GmbH
A7	Leicher, T	2007	KUE 13183B-N,N-dimethylsulfamid (technical; metabolite): Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil.	Bayer CropScience AG	LRT-Rg-R-31/07,	-	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1..2	Schad, T.	2001b	Predicted environmental concentrations of tolylfluanid and tolylfluanid-dimethylaminosulfotoluidide (DMST) in groundwater recharge based on calculations with FOCUS-PELMO, Use in apples, grapes, strawberries.	Bayer AG	MR-044/01	No	No	Yes	LANXESS Deutschland GmbH

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A7.1.1.1.1	Erstling, K.	2001	Abiotic Degradation.	Bayer AG	G 01/014 2/01 LEV	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.1	Feldhues, E.	2005	Material balance of Preventol A 5S after hydrolysis in demineralised water	Bayer AG	2005/0 153/02	No	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.1	Jungheim, M.	2001a	Preventol A5-S. Abiotic degradation (pH 4, 7, 9).	Bayer AG	A 00/015 3/00	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.1	Jungheim, M.	2001b	Preventol A5-S. Abiotic degradation (pH 8, pH 8.2).	Bayer AG	A 00/01 53/02	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.1	Jungheim, M.	2001c	Preventol A5-S. Abiotic degradation (pH 5).	Bayer AG	A 00/01 53/03	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.1	Jungheim, M.	2001d	Preventol A5-S. Abiotic degradation (pH 6).	Bayer AG	A 00/01 53/01	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.1.1.1.1	Schöfer, S.	2002a	Clarification to the report of a hydrolysis study conducted by Suzuki & Yoshida (1994).	Bayer AG	M9494 (MR-437/02)	No	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.1	Scholz, K.	1988b	Metabolism of [benzene ring-U-14C] tolylfluanid (Euparen M) in soil under aerobic conditions.	Bayer AG	PF2984	No	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.1	Suzuki, M.; Yoshida, K.	1994	Identification of transformed compound produced in ready biodegradability test of Preventol A-5.	Mitsubishi -kasei Institute, Japan	M9494	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.1	Wilmes, R.	1982a	Fate/behaviour of crop protection products in water.	Bayer AG	M1093	No	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.1	Wilmes, R.	1982b	Properties of Pesticides in Water, Hydrolytic Stability - Euparen (Dichlofluanid).	Bayer AG	MR 86003	No	No	Yes	LANXESS Deutschland GmbH

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A7.1.1.1.2	Hellpointner, E.	1992	Assessment of the environmental half-life of the direct photodegradation of Tolylfluanid in water.	Bayer AG	PF-3661	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.1.2	Hellpointner, E.	2000	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of DMST in water.	Bayer AG	MR-573/99	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1	Mueller, G.	1998b	DMSA Biodegradation.	Bayer AG	689A/97O	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1	Mueller, G.	1999	Investigation of the ecological properties of DMSA. (DMSA biodegradation).	Bayer AG	770A/98	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.1.1.2.1	Schöfer, S.	2002b	Statement on the validity of the study "Yoshida, K. (1992): Ready biodegradability test of Preventol A-5, Bayer report No. 1B5046".	Bayer AG	MR-450/02	No	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1	van Ginkel, G.G.; Stroo, C.A.	2000	Biodegradability of Preventol A4S in the Closed Bottle Test.	Akzo Nobel, The Netherlands	CGS-ENV F00057 T 00003 C	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.1	Scholz, K.	1997a	Aerobic degradation of Tolylfluanid in Water-Sediment.	Bayer AG	PF-4242 (MR 647/97)	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.1	Scholz, K.	1997b	Aerobic degradation of Dichlofluanid in Water-Sediment.	Bayer AG	4319 (MR-948/97)	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2	Hardy, I.A.J.; Patel, M.	2005	Dichlofluanid: Kinetic Modelling Analysis of Data from Two Water Sediment Studies.	Batelle UK Ltd., UK	CX/05/058	No	No	Yes	LANXESS Deutschland GmbH

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A7.1.2.2.2	Krauskopf, B.	1995	Calculation of DT50- and DT90-values of DMST in two water/sediment-systems.	Bayer AG	M9194	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2	Schad, T.	2001a	Calculation of half-lives of tolylfluanid and its metabolite DMST generated by aerobic water-sediment systems.	Bayer AG	MR-517/00	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2	Schad, T.	2002	Calculation of DT50 of tolylfluanid-dimethylsulfotoluidide (DMST) generated in aerobic water-sediment systems.	Bayer AG	MR-467/02	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2	Scholz, K.	1987a	Degradation of Tolylfluanid in the Water-Sediment System.	Bayer AG	PF-2783	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2	Scholz, K.	1987c	Degradation of Dichlofluanid in Water-Sediment Systems.	Bayer AG	2800 (IM 1257)	No	No	Yes	LANXESS Deutschland GmbH

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A7.1.2.2.2	Scholz, K.	1988a	Degradation of plant protectants in the water-sediment system.	Bayer AG	PF2987	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2.	Sneikus, J. .	2007a	[N-methyl-14C]Tolylfluanid: Aerobic Aquatic Degradation.	Bayer CropScience AG, Development Metabolism/Environmental Fate, Monheim, Germany. ,	MEF-07/319	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.1.2.2.2.	Sneikus, J.	2007b	[N-methyl- 14 C]Dimethylsulfamide: Aerobic Aquatic Degradation.	Bayer CropScience AG, Development Metabolism/Environmental Fate, Monheim, Germany.	MEF-07/222,	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.3	Sommer, H.	2000	Estimation of the adsorption coefficient (Koc) of Tolylfluanid on soil using High Performance Liquid Chromatography (HPLC).	Bayer AG	MR-428/00	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.4	Dorgerloh M.; Sommer, H.	2001	Euparen M WG 50 - Indoor Microcosm (Water/Sediment) with Rainbow Trout (*Oncorhynchus mykiss*) Simulating Multiple Applications.	Bayer AG	DOM 20076	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.1.4	Simmonds, M.B.	2003 (amend. 2003)	[^{14}C]DMST – Adsorption to and Desorption from One Marine and One Fresh Water Sediment.	Batelle AgriFood Ldt., United Kingdom	CX/02/081	Yes	NO	Yes	LANXESS Deutschland GmbH
A7.2	Schuphan, I.; Ebing, W.	1979	Overall result of studies to investigate fate of Euparen M WP (Tolylfluanid) in soil (Laboratory degradation studies).	Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA), Germany	FM226	No	No	Yes	LANXESS Deutschland GmbH
A7.2.2.1	Schäfer, H.	1995	Calculation of DT-50 values of the Tolylfluanid metabolite dimethylamino-sulfotoluidide in soil under aerobic conditions.	Bayer AG	MR-875/95	No	No	Yes	LANXESS Deutschland GmbH

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A7.2.2.1	Stupp, H. P.; Augustin, T..	2007a	[N-methyl-14C]tolylfluanid: Aerobic soil metabolism in four soils from EU,	Bayer CropScience AG, Edition Number: M-289076-01-1, -13.	MEF-07/208,	No	No	Yes	LANXESS Deutschland GmbH
A7.2.2.1	Sur, R.	2007a	Kinetic evaluation of the aerobic soil metabolism of tolylfluanid, DMST, DMST-acid, and dimethylsulfamide for the determination of modelling endpoints. Edition Number: M-288456-01-1, unpublished, date: 2007-06-06	Bayer CropScience	MEF-07/204,	No	No	Yes	LANXESS Deutschland GmbH

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A7.2.2.1	Sur, R.	2007b	Kinetic Evaluation of the Aerobic Aquatic Metabolism of Tolylfluanid, DMST, DMST-acid, and Dimethylsulfamide,	Bayer CropScience AG, Development Metabolism/Environmental Fate, Monheim, Germany.	MEF-07/314	No	No	Yes	LANXESS Deutschland GmbH
A7.2.3.1	Brumhard, B.	1997	Adsorption/desorption of DMST on four soils.	Bayer AG	PF4104	Yes	No	Yes	LANXESS Deutschland GmbH
A7.2.3.1	Stupp, H. P.	2007b	N,N-Dimethylsulfamide: Adsorption/desorption on five soils.	Bayer CropScience AG, MEF-07/226, Edition Number: M-289344-01-1,	MEF-07/226	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.2.3.2	Scholz, K.	1987b	Leaching characteristics of Tolylfluanid (Euparen M) aged in soil.	Bayer AG	PF2864	No	No	Yes	LANXESS Deutschland GmbH
A7.3.1	Hellpointner, E.	1995 (amend. 1999)	Calculation of the chemical lifetime of tolylfluanid in the troposphere.	Bayer AG	PF4097	Yes	No	Yes	LANXESS Deutschland GmbH
A7.3.1	Hellpointner, E.	1997	Calculation of the chemical lifetime of Dichlofluanid in the troposphere.	Bayer AG	PF-4305	No	No	Yes	LANXESS Deutschland GmbH
A7.4.1.1	[redacted]	2007	Acute toxicity of tolylfluanid - N,N – dimethylsulfamid to fish (Rainbow trout, Oncorhynchus mykiss) under static conditions, limit test.	[redacted]	EBKUL001	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.1	[redacted]	1989a	Acute toxicity of Euparen M WG 50 to rainbow trout (*Salmo gairdneri*) in a flow-through test.	[redacted]	FF-259	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.1.1	[redacted]	2001	Dimethylsulfotoluidid (DMST): Acute toxicity test with rainbow trout (*Oncorhynchus mykiss*) under static conditions.	[redacted]	1022.007.103	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.1	[redacted]	1979	Fish toxicity - Dichlofluanid = KUE 13 032 C - rainbow trout.	[redacted]	FF-74	No	No	Yes	LANXESS Deutschland GmbH
A7.4.1.1	[redacted]	1980	Fischtoxizitaet - Dichlofluanid = KUE 13032C - Goldorfe.	[redacted]	FO-288	No	No	Yes	LANXESS Deutschland GmbH
A7.4.1.1	[redacted]	1964	Effects of pesticides on marine animals.	[redacted]	14804	No	Yes	Yes	US Department of the Interior, Fish and Wildlife Service

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A7.4.1.1	[redacted]	2001c (amend. 2003)	Acute Toxicity of Dimethylaminosulfotoloidid (DMST) to the Sheepshead Minnow, Cyprinodon variegatus, Determined Under Static Test Conditions.	[redacted]	46731	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.1	[redacted]	2004a	Preventol A 4-S – Fish (Sheepshead Minnow), Acute Toxicity Test. Static, 96 h.	[redacted]	FAS91231	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.1	[redacted]	1986a	Acute flow-through toxicity of Preventol A 4-S to Rainbow Trout (Salmo gairdneri).	[redacted]	779	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.1	[redacted]	1986b	Acute flow-through toxicity of Preventol A 4-S to Bluegill Sunfish (Lepomis macrochirus).	[redacted]	780	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.1.2	[redacted]	2007a	Acute Toxicity of KUE 13183B- N,N - dimethylsulfamid (tech.) to the Waterflea Daphnia magna in a Static Laboratory Test System - Limit Test	[redacted]	. EBKUL003	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.2	[redacted]	2007b	Influence of KUE 13183B-N,N-dimethylsulfamid (tech.) on Development and Reproductive Output of the Waterflea Daphnia magna in a Static Renewal Laboratory Test System	[redacted]		Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.2	Caspers, N.	1997a	DMSA - Acute Daphnia Toxicity.	Bayer AG	689A/97D	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.2	Forbis, A.D.	1986	Acute flow-through toxicity of Preventol A 4-S to Daphnia magna.	ABC Laboratories Inc., USA	778	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.1.2	Heimbach, F.	1995a	Acute toxicity of DMST to Water Fleas (*Daphnia magna*).	Bayer AG	HBF/Dm 149	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.2	Hendel, B.; Sommer, H.	2001	Acute Toxicity of Tolylfluanid (tech.) under Flow Through Test Conditions to Water fleas (*Daphnia magna*).	Bayer AG	HDB/Dm 246	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.2	Madson, T.J.	2001d (amend. 2003)	Toxicity of Dimethylaminosulfotoluidid (DMST) on New Shell Growth of the Eastern Oyster (*Crassostrea virginica*).	ABC Laboratories, USA	46732	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.2	Madson, T.J.	2001e (amend. 2003)	Acute Toxicity of Dimethylaminosulfotoluidid (DMST) to the Mysid Shrimp, *Mysidopsis bahia,* Determined under Static Test Conditions.	ABC Laboratories, USA	46733	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.1.3	Anderson, J.P.E.	1995	Influence of Tolylfluanid on the Growth of the Green Alga, *Scenedesmus subspicatus*.	Bayer AG	AJO/13 3495	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3	Anderson, J.P.E.	1997	Influence of Euparen M WG 50 on the Growth of the Green Alga, *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*).	Bayer AG	AJO/15 8097	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3	Caspers, N.	1997b	DMSA - Alga Growth Inhibition Test.	Bayer AG	689A/9 7Al	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3	Grade, R & Wydra, V	2007	Toxicity of KUE 13183B-N,N-dimethylsulfamid to Pseudokirchneriella subcapitata in an Algal Growth Inhibition Tes	Bayer AG	342612 1	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.1.3	Heimbach, F.	1985	Growth Inhibition of Green Algae (Scenedesmus subspicatus) by Dichlofluanid (90 % Premix).	Bayer AG	HBF/Al 13	No	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3	Madson, T.J.	2001a (amend. 2003)	Toxicity of Dimethylaminosulfotoluidid (DMST) to the Freshwater Diatom, *Navicula pelliculosa.*	ABC Laboratories, USA	46672	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3	Madson, T.J.	2001b (amend. 2003)	Toxicity of Dimethylaminosulfotoluidid (DMST) to the Saltwater Diatom, *Skeletonema costatum.*	ABC Laboratories, USA	46673	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3	Madson, T.J.	2002 (amend. 2003)	Toxicity of Dimethylaminosulfotoluidid (DMST) to the Blue-Green Alga, *Anabaena flos-aquae.*	ABC Laboratories, USA	46671	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.1.3	Ritter, A.	1989a	Toxicity of Euparen WG 50 to Scenedesmus subspicatus (OECD Algae Growth Inhibition Test).	RCC Umweltchemie AG, Switzerland	235260	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3	Scheerbaum, D.	2004c	Preventol A 4-S – Alga, Growth Inhibition Test with *Skeletonema costatum*, 96 h.	Dr. U. Noack-Laboratorium für angewandte Biologie, Germany	SSC91231	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.4	Caspers, N. Mueller, G.	1999	Investigation of the ecological properties of Tolylfluanid.	Bayer AG	851 A/99	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.4	Mueller, G.	1998a	Toxicity of DMST Pt. 203743904 to bacteria.	Bayer AG	81131930	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.2	[redacted]	1991	Tolylfluanid - Bioconcentration in Fish.	[redacted]	BF-007 (M 7747)	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.3	[redacted]	2002a	Effects of multiple applications of Tolylfluanid WG50 on rainbow trout in outdoor microcosm enclosures.	[redacted]	HBF/Mt 14	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3	Heimbach, F.; Brock, T.C.M.; Arts, G.H.P.; Deneer, J.W.	2002b	Effects of multiple applications of Tolylfluanid WG50 on the aquatic community in outdoor microcosm enclosures.	Bayer AG	HBF/Mt 13	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3	Hendel, B.	2001c	Extended laboratory Study on Effects and Recovery of a *Daphnia magna* Population in a Water-Sediment System after Application of Tolylfluanid WG 50.	Bayer AG	HDB/eDm06	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.3.1	Anderson, J.P.E.	1998a	Influence of DMST on the Growth of the Green Alga *Pseudokirchneriella subcapitata* formerly *Selenastrum capricornutum*.	Bayer AG	AJO/16 6497	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.1	Grau, R.	1989b	Toxicity of Tolylfluanid techn. to rainbow trout (Salmo gairdneri) with prolonged exposure (21 days).	Bayer AG	FF-273	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.1	[redacted]	1989c	Toxicity of Euparen M WG 50 to rainbow trout (Salmo gairdneri) with prolonged exposure (21 days).	[redacted]	FF-265	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.3.1	[redacted]	1989d (amend. 2005)	Toxicity of Dichlofluanide techn. (VM 90) for Rainbow Trout (Salmo gairdneri) with prolonged exposure (21 days); including Amendment No.1 to report, from Dr Grau, Bayer CropScience AG, dated 24th August 2005.	[redacted]	FF-246	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.1	[redacted]	1990	Toxicity of DMSA for Rainbow Trout (*Oncorhynchus mykiss*) with prolonged exposure (21 days).	[redacted]	FF-290	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.2	[redacted]	2007	Chronic Toxicity (28 days) of KUE 13183B - N,Ndimethylsulfamid (techn.) to Fish (Oncorhynchus mykiss) under Semi-Static Conditions	[redacted]	EBKUL002	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.3.2	[redacted]	2000	DMST - Chronic toxicity (21 days) to juvenile rainbow trout (*Oncorhynchus mykiss*) in a semi-static test.	[redacted]	DOM 20034	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.2	[redacted]	2000	Dimethylsulfotoluidid (DMST): Early life-stage toxicity test with fathead minnow (*Pimephales promelas*) under flow-through conditions.	[redacted]	1022.007.122	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.2	[redacted]	2006a	Early Life Stage Toxicity of Dichlofluanid Technical to the Fathead Minnow (*Pimephales promelas*) Under Flow-Through Conditions	[redacted]	EBDFX 004	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.4	Heimbach, F.	1997	Influence of DMST on the Reproduction Rate of Water fleas (*Daphnia magna*).	Bayer AG	HBF/rD m 60	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.3.4	Hendel, B.	2001a	Influence of Tolylfluanid (tech.) on the Reproduction Rate of Water Fleas.	Bayer AG	HDB/rDm 66	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.4	Hooftman, R. N.; Kaufman-van Bommel, J.; Bent- van Dalsum, M.	1989	Reproduction test with Euparen M WG and daphnia magna.	TNO Division of Technology for Society, The Netherlands	R 89/335a	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.4	Kern, M.E.; Nieden, D.; Lam, C.V.	2006b	Chronic Toxicity of Dichlofluanid Technical to the *Dapnia magna* Under Flow-Through Conditions	Bayer CropScience AG	EBDFX 003	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.5.1	[redacted]	2003	Acute Toxicity of Dimethylaminosulfotoluidid (DMST) to the Marine Amphipod, *Leptocheirus plumulosus*	[redacted]	48165	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.3.5.1	Heimbach, F.	1995b	Influence of DMST on Development and Emergence of Larvae of *Chironomus riparius*.	Bayer AG	HBF/CH 08	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.5.1	Heimbach, F.	1999b	Influence of Dimethylaminosulfanilid (DMSA) on Development and Emergence of Larvae of Chironomus riparius in a Water-Sediment System.	Bayer AG	HBF/Ch 31	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.5.1	Hendel, B.	2001b	Influence of DMST (tech.) on Development and Emergence of Larvae of *Chironomus riparius* in a Water-Sediment System.	Bayer AG	HDB/Ch 46	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.3.5.1	Scheerbaum, D.	2004b	Preventol A 4-S – Amphipod (*Corophium volutator*), Acute Toxicity Test, Static, 10 d Limit Test in a Water-Sediment System.	Dr. U. Noack-Laboratorium für angewandte Biologie, Germany	DCA91231	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.5.2	Madson, T.J.	2001f (amend. 2003)	Toxicity of Dimethylaminosulfotoluidid (DMST) to Duckweed, *Lemna gibba G3,* Determined under Static Test Conditions.	ABC Laboratories, USA	46734	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.1	Anderson, J.P.E.	1998b	Influence of Euparen M (Tolylfluanid) WG 50 on glucose stimulated respiration in soils.	Bayer AG	AJO/18 3198	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.1	Anderson, J.P.E.	1998c	Influence of Euparen M (Tolylfluanid) WG 50 on the microbial mineralization of nitrogen in soils.	Bayer AG	AJO/18 3298	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.5.1.1	Anderson, J.P.E.	2000	Influence of the Metabolite KUE 13183B-Dimethylsulfotoluidid (DMST) on the Microbial Mineralization of Nitrogen in Soils.	Bayer AG	AJO/21 1200	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.1	Anderson, J.P.E.	2001a	Influence of Euparen M (Tolylfluanid) WG 50 on Glucose Stimulated Respiration in Soils.	Bayer AG	AJO/21 9901	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.1	Anderson, J.P.E.	2001b	Influence of Euparen M (Tolylfluanid) WG 50 on the Microbial Mineralization of Nitrogen in Soils.	Bayer AG	AJO/22 0001	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.1	Anderson, J.P.E.	2001c	Influence of the Metabolite KUE 13183B-Dimethyl-sulfotoluidid (DMST) on the Microbial Mineralization of Nitrogen in Soils.	Bayer AG	AJO/22 0101	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.5.1.1	Schulz,L.	2007	Effects of KUE 13183B-N,N-dimethylsulfamid on the activity of soil microflora (Nitrogen transformation test).	BioChem agrar - Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany	07 10 48 009 N,	-	No	Yes	LANXESS Deutschland GmbH
A7.5.1.2	Heimbach, F.	1989	Toxicity of Euparen M WG 50 to Earthworms.	Bayer AG	HBF/RG 102	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.2	Heimbach, F.	1995c	Acute toxicity of tolylfluanid (techn.) to earthworms.	Bayer AG	HBF/Rg 217	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.3	Fiebig, S.	2001a	Tolylfluanid WG 50, Terrestrial Plants Toxicity, Seedling Emergence, Tier II.	Dr. U. Noack-Laboratorium für Angewandte Biologie, Germany	TNK73865 (Project No. 000627 BK)	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.5.1.3	Fiebig S.	2001b	Tolylfluanid WG 50, Terrestrial Plants Toxicity, Vegetative Vigor, Tier II.	Dr. U. Noack-Laboratorium für Angewandte Biologie, Germany	TNW73 863 (Project No. 000627 BK)	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.3	Meisner, P.; Kolb, U.	2000	Herbicidal Screening Data for Euparen M WG 50.	Bayer AG	MPE NTP 05/00	No	No	Yes	LANXESS Deutschland GmbH
A7.5.2.1	Heimbach, F.	1999a	Influence of tolylfluanid WG 50 on the reproduction of earthworms (*Eisenia fetida*).	Bayer AG	HBF/RG 296	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.2.1	Meisner P.	2000	Influence of Dimethylsulfotoluidid (DMST) on the Reproduction of Earthworms (*Eisenia fetida*).	Bayer AG	MPE/Rg 339/00	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.5.3.1.1	[redacted]	2000	TOLYLFLUANID techn. a.i.: Acute Oral Toxicity for Bobwhite Quail.	[redacted]	BAR/LD 031	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.3.1.1	[redacted]	1973	KUE 13183 b - Acute Oral Toxicity to Quail.	[redacted]	V-73263	No	No	Yes	LANXESS Deutschland GmbH
published	Callow, M.E.; Finlay, J.A.	1995	A simple method to evaluate the potential for degradation of antifouling biocides. *Biofouling,* Vol 9 (2) pp 153-165	-	-	No	Yes	No	-

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published	ECB	2003	TGD for Risk Assessment: Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Commission Directive 98/8/EEC concerning the Placing of Biocidal Products on the market	-	-	No	Yes	Yes	-
published	Ehling, U.H.; Machemer, L.; Buselmaier, W.; et al.	1978	Standard protocol for the dominant lethal test on male mice set up by the work group "Dominant Lethal Mutations of the ad hoc Committee Chemogenetics". *Arch. Toxicol.* **39(3)**: 173-85	-	-	No	Yes	No	-

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published	Kumpulainen, J.; Koivistoinen, P.	1977	Fluorine in Foods. Residue Reviews 68: 37-57	-	-	No	Yes	Yes	-
published	WHO	1970	WHO Chronicle. Fluorides and Human Health. 24: 271-280	-	-	No	Yes	No	-
published	WHO	2002	International Programme on Chemical Safety (IPCS) - Fluorides. Environmental Health Criteria 227.	-	-	No	Yes	No	-