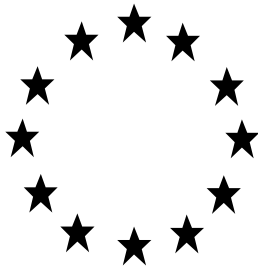
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Tolylfluanid

Product-type 7

(Film preservatives)

January 2016

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 7 (Film preservatives), 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-types 7 (Film preservatives), 8 (Wood preservatives) and 21 (Antifouling products).

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 7 was 31 October 2008, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 28 October 2008, 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 16 December 2008.

On 17th March 2015, the Rapporteur Member State submitted to the ECHA 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 7, 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.

[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

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

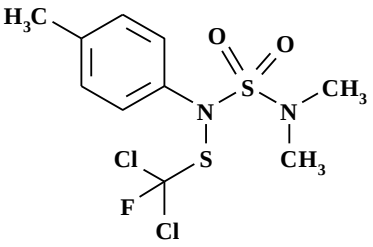
However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1 PRESENTATION OF THE ACTIVE SUBSTANCE

2.1.1 IDENTITY, PHYSICO-CHEMICAL PROPERTIES AND 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

2.1.2 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.

The missing parts of information on physical/chemical properties of the representative product should be provided at product authorisation. For the analytical method for the determination of tolylfluanid in the biocidal product, the specificity of the method should be demonstrated for the product.

For PC properties of metabolites of tolylfluanid, see DOC IIA and LoEP.

2.1.3 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. Acceptable analytical method for detection and identification of N,N-dimethylsulfamide in water is also given in DocIIA. There are no other impurities of toxicological or environmental concern in the technical grade material. For impurities in the active substance, see the Confidential Annex. The limit of quantification for tolylfluanid and DMST in water is 0.05 µg/L and for N,N-DMS 0.025 µg/L. The limit of quantification for tolylfluanid and DMST in soil is 0.01 mg/kg. For tolylfluanid the limit of quantification in air is 0.01 mg/m^3. Limits of quantification in analytical methods are in general at sufficiently low level compared with Predicted-No-Effect-Concentrations (PNEC) in different environmental compartments (soil and surface water) and human health aspects (air and potable water).

Methods for residue analysis in animal and human body fluids and tissues were agreed to be submitted (PT 21) 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.

2.1.4 INTENDED USES

Tolylfluanid in PT7 is intended to be used mainly against mould to protect paint film coating on wooden surface met in use class 2 and 3. 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.

2.1.5 EFFICACY

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. According to an agar diffusion test with an internal method No. 2304-0600101-05E of LANXESS Deutschland GmbH tolylfluanid at a concentration of 0.20 % in a coating formulation (JJT 4498) without ageing and at a concentration of 0.30% in a coating formulation (JJT 4498) with ageing is efficient against mould growth. According to the applicant the internal test method has been developed in accordance with the standardized test method DIN EN 15457_2007-10. Applicant states that the internal method does not follow the standard completely, and is even more stringent than DIN EN 15457_2007-10. Based on a submitted data it can be concluded that 0.20-0.30% of tolylfluanid in end-product (treated article under BPR) will likely be efficacious towards target organisms. However, additional tests on in-use conditions should be performed at product authorization stage.

Based on the unspecific mode of action a development of resistance is not expected nor has been ever observed. The Fungicide Resistance Action Committee (FRAC) lists (2007) tolylfluanid in group M6 (= multi-site contact activity / sulfamides) together with the comment: "generally considered a low risk group with no signs of resistance developing to the fungicides / No cross resistance between the group members".

2.1.6 CLASSIFICATION AND LABELLING

The current harmonised classifications and labellings for Tolylfluanid containing < 0.1% (w/w) of particles with an aerodynamic diameter below 50µm (Index No 613-116-01-4) and Tolylfluanid containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm (Index No 613-116-00-7) according to Regulation (EC) No 1272/2008 (CLP Regulation) are presented below.

Table 1. Tolylfluanid containing < 0.1%(w/w) of particles with an aerodynamic diameter below 50µm (Index No 613-116-01-4) according to CLP Regulation.

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Eye Irrit. 2 H319 STOT SE 3 H335 Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Acute 1 H400
Labelling	
Pictograms	GHS07, GHS09
Signal Word	Warning
Hazard Statement Codes	H319: Causes serious eye irritation. H335: May cause respiratory irritation. H315: Causes skin irritation. H317: May cause an allergic skin reaction H400: Very toxic to aquatic life.
Specific Concentration limits, M-Factors	M = 10 (Aquatic acute 1)

Table 2. Tolylfluanid containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm (Index No 613-116-00-7) according to CLP Regulation.

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 2* H330 STOT RE 1** H372 Eye Irrit. 2 H319 STOT SE 3 H335 Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Acute 1 H400
Labelling	
Pictograms	GHS05, GHS09
Signal Word	Danger
Hazard Statement Codes	H330: Fatal if inhaled. H372: Causes damage to organs through prolonged or repeated exposure. H319: Causes serious eye irritation. H335: May cause respiratory irritation, H315: Causes skin irritation. H317: May cause an allergic skin reaction. H400: Very toxic to aquatic life.
Specific Concentration limits, M-Factors	M = 10 (Aquatic acute 1)

Tolylfluanid is already approved for product type 8 (Commission Directive 2009/151/EC) and product type 21 (Commission Implementing Regulation (EU) 2015/419) where it was

agreed that the assessment covered both entries of tolylfuanid, as the distintion between the two classifications is relevant only in exceptional situations in which the dry form of the substance is available.

Regarding environment Aquatic Chronic 1 H410 with M=1 (Aquatic Chronic 1) classification is proposed according to Regulation (EC) No 286/2011. This is based on a NOEC of 0.00265 mg/l for *Daphnia magna.*

Under the CLP Regulation a distinction can be made between category 1A and 1B for the classification as a skin sensitizer. This was not required under the previous dangerous substances legislation under which tolylfluanid was classified sensitizer R43. Tolylfluanid is not a highly potent sensitizer. Based on information available, there is no certainty on whether tolylfluanid could be classified other than category 1. In the single high-reliability compliant key study (Buehler assay) tolylfluanid was negative for skin sensitizing properties. The two other studies suggesting category 1A (GPMT) or a significant sensitizing property (open epicutaneous test, a key study) are of lower reliability or based with a non-compliant guideline according to current Guidance on the Application of the CLP criteria, respectively. Based on the Buehler assay and other information, including human data, the sub-category is proposed to be at least 1B.

Classification and labelling of the representative product containing 46% tolylfluanid based on CLP regulation is presented in the Table 3.

Table 3. Classification and labelling of the representative product containing 46% tolylfluanid

GSH Pictogram(s) and Code(s)	GHS07, GHS09
Hazard Class and Category Code(s)	Eye Irrit. 2 H319 Skin Irrit. 2 H315 STOT SE 3 H335 Skin Sens. 1 H317 Aquatic Acute 1 H400 Aquatic Chronic 2 H410
Hazard Statements	H319: Causes serious eye irritation. H315: Causes skin irritation. H335: May cause respiratory irritation. H317: May cause an allergic skin reaction. H410: Very toxic to aquatic life with long-lasting effects.

Precautinary statements	P261: Avoid breathing dust. P264: Wash hands thoroughly after handling. P271: Use only outdoors or in the well-ventilated area. P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312: Call a POISON CENTER or doctor/physican if you feel unwell. P321: Specific treatment (see … on this label) P332+P313: If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362: Take off contaminated clothing and wash before use. P363: Wash contaminated clothing before reuse. P391: Collect spillage. P403+P233: Store in well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/container to … [… in accordance with local/regional/national/international regulation (to be specified)].
Signal Word	Warning

2.2 SUMMARY OF THE RISK ASSESSMENT

2.2.1 HUMAN HEALTH RISK ASSESSMENT

2.2.1.1 SUMMARY OF MAMMALIAN TOXICITY STUDIES

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) and PT 21 (Antifouling products). The following text on hazard identification of tolylfluanid has been taken from the AR of tolylfluanid for PT 8 and PT 21, 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 4.

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 histopathological 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.

<u>Health Hazards of the Representative Product</u>

For classification of the representative product, see Table 3 above. For health hazards, see Doc IIB. The relevant LOAEL/LOAEC and NOAEL/NOAEC settings are represented in the Table 4 and selected critical endpoints are highlighted with grey colour.

Table 4. 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 reference doses for the systemic toxicity of tolylfluanid can be defined, with relevance to assessment of risks associated with exposure to preservatives in paints and adhesives. The risks are related to the length of exposure and take into accoung the most relevant adverse health effects expected on the basis of animal studies. The most relevant studies for setting the AEL values were considered to be the 2-year oral study in rat (Leser et al., 1996) for the long term exposure and the teratogenic study in rabbit (Holzum 1991b) for the short term exposure. The medium-term AEL is identical to the long-term AEL. The safety factor of 100 was used in deriving the reference values. The reference values and the relevant NOAEL-values are summarised in Table 5. The reference values are applicable both to primary exposure in professional and non-professional use, as well as to secondary exposure.

Table 5. 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	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.

2.2.1.2 SUMMARY OF THE HUMAN EXPOSURE ESTIMATIONS

The exposure assessments have been carried out on products containing 46% (biocidal product) and 0.7 - 0.9% (end-use product) tolylfluanid.

Local effects

Tolylfluanide is classified as skin sensizer and eye and skin irritant according to the Regulation (EC) No 1272/2008. It may also cause respiratory irritation. Qualitative local risk characterization was performed for local effects (Doc II-C, Section 1.3.2).

Primary Exposure

The potential exposure of an operator through ingestion is considered negligible and has therefore not been pursued further. Operator exposure through inhalation is low (due to the low vapour pressure of tolylfluanid) but has been included in the exposure assessments. The majority of the exposure occurs via dermal absorption. A value of 25% or 15% for dermal absorption of tolylfluanid from solvent-based product data was used and the body weight of the operator was taken as 60 kg.

Table 6 summarises the results of the exposure assessment for professional/industrial and amateur users. The detailed assessments can be found in Doc II-B, Sections 3.2.2 and 3.2.3.

Table 6. Exposure during industrial, professional and amateur use of tolylfluanid

Scenario	Total systemic exposure [mg/kg bw/day]	
	TIER 1 (no PPE)	*TIER2 (with PPE)*
Industrial - Production of end-use products	*2.70*	*0.027*
Industrial - Maintenance of machines	*25.8*	*0.046**
Professional - Manual Dipping	*0.088*	*0.0088*
Professional - Mechanical Dipping	*0.27*	*0.027*
Cleaning out dipping tank	*0.018*	-
Professional - Spraying (incl. cleaning of the spray)	*1.74*	*0.095*
Professional - Brushing (incl. cleaning of the brush)	*0.84*	*0.13*
Professional - Handling of treated wet wood	*0.0046*	-
Amateur - Brushing indoors (incl. cleaning of the brush)	*0.76*	-
Amateur - Brushing outdoors (incl. cleaning of the brush)	*0.084*	-

* after rinsing the system

Secondary Exposure

Secondary exposure occurs to non-users and bystanders. A value of 15 % for dermal absorption of tolylfluanid from solvent-based product data was used and the body weight of an adult, toddler or infant was taken as 60 kg, 10 kg and 8 kg, respectively.

Table 7 summarises the results of the secondary exposure assessment.

Table 7. Secondary exposure to tolylfluanid

Scenario		Systemic dose [mg/kg bw/day]
Acute exposure	Adult (amateur) sanding coated wood (inhalation + dermal)	0.009
	Infant chewing wood off-cut	0.028
	Toddler - dermal contact with wet paint (dermal)	0.12
	Infant contacting wet paint and mouthing (ingestion + dermal)	0.21
Chronic exposure	Child -Chronic ihalation exposure to evaporated residues	negligible
	Adult cleaning work clothes at home (dermal)	0.11
	Adult (professional) sanding treated wood (inhalation + dermal)	0.046
	Infant playing on coated wood structures and mouthing (dermal)	0.0035

2.2.1.3 SUMMARY OF RISK CHARACTERISATION FOR HUMANS

Tolylfluanide is classified as skin sensitizer and eye and skin irritant according to the Regulation (EC) No 1272/2008. It may also cause respiratory irritation. The biocidal product is classified as eye and skin irritant and skin sensitizer. Qualitative local risk characterisation was done for the local effects. Worker dermal exposure during industrial production of end-use products is mostly excluded by the use of protective gloves and suitable coveralls. Tolylfluanide is not volatile with a vapour pressure of 2.00×10^{-4} Pa at 20 °C. Thus inhalation exposure is not relevant in this scenario. Maintenance of production machines can only be done after the rinsing the system prior to the maintenance work to get the consetration of active substance low enough. The use of gloves and coveralls is required in this task due to sensitizing property of tolylfuanid. The use of gloves is obligatory in all scenarios, in addition to coveralls and also RPE during spraying. The use of gloves is also required due to sensitizing property of tolylfluanid. Eye protectors are obligatory where splashes may occur. Professionals will be exposed during dipping, painting with brush or spraying equipment and handling of treated wet wood for tolylfluanide concentrations below the threshold for classification of the product as sensitizing, eye, skin or respiratory irritating according to the Regulation (EC) No 1272/2008. Non-professionals will also be exposed during painting with brush for tolylfluanide concentrations below the threshold for classification of the product as sensitizing, eye, skin or respiratory irritanting according to the Regulation (EC) No 1272/2008. Secondary exposure may occur also to the tolylfluanid concentration below the threshold for classification of the product as sensitizing, eye, skin or respiratory irritanting.

The comparison of the estimated exposure with the relevant limit values demonstrates that addition of tolylfluanid into coating formulations as film preservative is safe for industrial workers with appropriate personal equipment (Table 8).

The use of tolylfluanid as film preservative and industrial application does not involve non-professional users. The exposure to the a.s. in industrial setting is typically chronic and the long-term AEL of 0.18 mg/kg bw/day is used to charterise the risk associated with this exposure.

Table 8. Risk assessment for primary exposure to tolylfluanid in PT7, industrial use

Scenario	PPE	NOAEL [mg/kg bw/day]	AEL [mg/kg bw/day]	Systemic exposure [mg/kg bw/day]	MOE	% AEL
Industrial - Production of end-use products	No	18	0.18	2.70	7	1500
	Gloves, coated coveralls	18	0.18	0.027	670	15
Industrial - Maintenance of machines	No	18	0.18	25.8	<1	14000
	Rinsing, gloves, coated coveralls	18	0.18	0.046	390	26
Industrial/Professional - Manual Dipping	No	18	0.18	0.088	200	50
	Gloves, coated coveralls	18	0.18	0.0088	2050	5
Industrial/Professional - Mechanical Dipping	No	18	0.18	0.27	67	150
	Gloves, coated coveralls	18	0.18	0.027	670	15
Cleaning out dipping tank	No	25	0.25	0.018	1400	7

Grey colour means unacceptable risk

Primary professional use of tolylfluanid containing coatings or professional handling of treated wet wood does not pose a risk (Table 9). Primary non-professional exposure during brush painting is not acceptable indoors, but is acceptable outdoors. Gloves and appropriate coveralls are required with brushing and spraying and in addition RPE with spraying.

Non-professional exposure from application of tolylfluanid-containing coatings is considered short-term exposure that is thought to occur only few days during the year. The short-term AEL of 0.25 mg/kg bw/day is used for risk characterization. The same use made by professionals is chronic exposure due to frequent and long (many years) use and the long-term AEL is appropriate reference valued for risk assessment.

Secondary (indirect) exposure may occur by coating removal by sanding, ingestion of coating chips or dermal contact with wet paint and mouthing. Coating removal by non-professional is short-term exposure and by professionals chronic exposure. Cleaning of coveralls made by professionals is chronic exposure to tolylfluanid. Chronic inhalation exposure to evaporated residues of tolylfuanid is negligible. Infant chronic dermal and oral exposure when playing on weathered (playground) structure is smaller than acute scenario dermal contact with wet paint and mouthing. All other secondary exposures are short-

term. Consequently, the short-tem AEL (0.25 mg/kg bw/day) is used to characterise the risk associated with these exposures. The secondary exposure to tolylfluanid in coatings does not pose a risk to non-porfessionals or professionals (Table 10).

Table 9. Risk assessment for primary exposure to tolylfluanid in PT7, professional and non-professional use

Scenario	PPE	NOAEL [*mg/kg bw/day*]	AEL [*mg/kg bw/day*]	Systemic exposure [*mg/kg bw/day*]	MOE	% AEL
Professional - Spraying (including cleaning of the spray)	No	18	0.18	1.74	10	970
	Gloves, impermeable coveralls, RPE (PF=10)	18	0.18	0.095	190	50
Professional - Brushing (including cleaning of the brush)	No	18	0.18	0.84	21	470
	Gloves, coated coveralls	18	0.18	0.13	140	70
Professional - Handling of treated wet wood	No	18	0.18	0.0046	3900	3
Amateur - Brushing indoors (including cleaning of the brush)	No	25	0.25	0.76	33	300
Amateur - Brushing outdoors (including cleaning of the brush)	No	25	0.25	0.084	300	34

Grey colour means unacceptable risk

Table 10. Risk assessment for secondary exposure to tolylfluanid in PT7, professional and non-professional use

Scenario	Systemic dose [mg/kg bw/day]	AEL [mg/kg /day]	% AEL	NOAEL [mg/kg /day]	MOE
Acute exposure					
Adult (amateur) sanding coated wood (inhalation + dermal)	0.009	0.25	4	25	2800
Infant chewing wood off-cut	0.028	0.25	11	25	890
Toddler - dermal contact with wet paint (dermal)	0.12	0.25	50	25	210
Infant contacting wet paint and mouthing (ingestion + dermal)	0.21	0.25	80	25	120
Chronic exposure					
Child -Chronic ihalation exposure to evaporated residues	negligible	0.18	-	18	-
Adult cleaning work clothes at home (dermal)	0.11	0.18	60	18	160
Adult (professional) sanding treated wood (inhalation + dermal)	0.046	0.18	30	18	390
Infant playing on coated wood structures and mouthing (dermal)	0.0035	0.18	2	18	5100

Combined exposure is the total exposure arising from individual tasks through different phases of use with a single product. Combined exposure to tolylfluanid at different stages of its service life is very unlikely and is not considered relevant.

Aggregated exposure covers exposure to a single chemical from multiple sources i.e. through primary exposure, secondary exposure and exposure to the same chemical in different producs and matrices through various routes of uptake. Tolylfluanid is used in biocidal products in the product types 8 (wood preservative) and 21 (antifoulings) in addition to the product type 7. However, primary exposure for professionals and non-professionals to these products are rare to occur for all product types. For produt type 7 it is not known whether consumer may use several paints containing tolylfluanid. To evaluate the aggregated exposure a very conservative approach where acute scenarios are compared with the long term AEL-value was chosen. By this way the repetive cumulative nature of consumer exposure to tolylfluanid containing products was assessed. For consumer scenario, brush painting is not acceptable scenario and it can be concluded that there is a concern.

Fluorine from tolylfluanid

In analogy to PT8 assessment, the amount of fluorine derived from the highest systemic dose in professional work was calculated. For the scenario for professional dipping and cleaning dipping tank without PPE, the scenario with the highest systemic tolylfluanid dose (0.15 mg/kg bw/day), the daily amout of fluoride (0.50 mg) was calculated. Hence, fluoride from tolylfluanid used in film preservatives does not pose a risk to humans.

Conclusion - tolylfluanid

The use of tolylfluanid in biocidal products and end-products can be considered safe for - professional and for the non-professional users when painting outdoors. The use of gloves and coveralls are obligatory and in addition eye-protectors where splashes may occur in industrial scenarios due to irritating and sensitizing property of tolylfluanid. The use of gloves, impermeable converalls and RPE are obligatory during spraying and gloves and coated coveralls druing production of end-use products, maintenance of machines, mechanical dipping and brushing. The use of gloves is recommended in all other primary professional scenarios. The secondary exposure to tolylfluanid in coatings does not pose a risk to non-professionals or professionals.

Tolylfluanid causes, however, concern to human health via drinking water use if water containing N,N-DMS is extracted for production of drinking water and ozonated. Tolylfluanid degrades to the persistent substance of N,N-DMS which may form N-nitrosodimethylamine (NDMA) during ozonation. The maximum transformation efficiency of 32% (in units of µg or µg/l) can be used in calculating of NDMA formation during ozonation. NDMA is genotoxic, mutagenic and carcinogenic (Carc Cat. 2) substance. NDMA has been classified by IARC in Group 2A "probably carcinogenic to humans" (IARC, 1987). In Doc IIA, see Ch. 3.14, information on ozone and strong other oxidizers was added but ozone is still the only known substance which is able to convert N,N-DMS into NDMA with efficiency.

Based on the groundwater risk assessment carried out by using PEARL 3.3.3 N,N-DMS concentrations exceed the groundwater limit value of 0.1 µg/l in eight of nine Focus scenarios (see Chapter 2.2.2-6 Risk characterisation for the environment – Groundwater). Calculated theoretical NDMA concentrations are also high and exceed the drinking water standard of 0.1 µg/l and the specific health based value (HBV) of 0.1 µg/l set for NDMA by the WHO and established intervention limit values of certain cities and countries, e.g. 10 ng/l (California), 9 ng/l (Ontario), 10 ng/l (Germany, UBA). Although groundwater is seldom ozonated as such, ozone can be used for removing impurities from raw water also in groundwater. In small municipalities, where surface water and groundwater are mixed, ozonation can take place after mixing.

The information on properties of N,N-DMS 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-DMS 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. At the same time it was agreed that drinking water limit value of 0.1µg/l shall be used in the risk assessment.

2.2.2 ENVIRONMENT

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 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 (2.0 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 0.9 days (21.5 hours) (24-hr day; 0.5E6OH/cm3) 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.

The photochemical half-life of DMST in air was 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 ON ENVIRONMENTAL ORGANISMS

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.

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 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 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.

N,N-DMS

$PNEC_{sediment\ fresh\ water}$ for N,N-DMS is 8 mg/kg ww (37 mg/kg dw). Value is derived from the equilibrium partitioning method with $PNEC_{freshwater\ r}$ of 10 mg/l according to the TGD (Part II), equation 70 and 88. Koc value of 1was used.

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.

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/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 ENDOCRINE DISTRUPTION ASSESSMENT

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).

2.2.2.5 EXPOSURE ASSESSMENT

Scenarios

Tolylfluanid has been evaluated as a film preservative (PT7) to protect paint film coatings on wooden surface in use classes[2] UC2 and UC3. Due to its instability in water tolylfluanid is currently only used in solvent-based products.

In the ESD for biocides of PT 7 "Environmental Emission Scenarios for Biocides used as Film Preservatives" (European Commission DG ENV/RIVM, 2004) no specific emission scenarios for coatings on wood are available. In this document it is stated that for the quantitative assessment of the emissions from paints and coatings to the environment all relevant scenarios of the ESD for biocides of PT 8 'Emission Scenario Document for Wood Preservatives (Parts 1 and 2) (OECD, 2003) have to be used. Where necessary the "Technical Guidance Document (TGD) for Risk Assessment" (European Commission, 2003) was also taken into consideration.

Emissions to the environment can occur during industrial application and subsequent storage due to *in situ* treatment and the service life. Uses of tolylfluanid in coatings include mainly amateur and professional brushing/painting outdoors. A further application of tolylfluanid is dipping and automated enclosed spraying which is mostly undertaken in joineries. There, treated wooden articles like fences, window frames etc. will be further processed and are not stored in an open outdoor area. In general, emissions to sewage water during these applications are not likely to occur, because e.g. dipping containers for solvent-based products are stand-alone devices without direct connection to the sewage. Residues and waste solvent from such dipping containers will be treated as special waste and not run into the sewage. Nevertheless, the OECD application and storage scenarios for dipping and automated spraying were provided for reasons of completeness, although they often are assumed be not in accordance with the EU regional legislation.

In addition to wood preservative scenarios mentioned above also city scenario (Leaching from paint, plasters, and fillers applied in urban areas, 2013) and direct emissions to surface water in urban areas scenarios (The assessment of direct emissions to surface water in urban areas (PT6.2/6.3 and 7-10, 2014) was used. Regarding the city scenario WGIV 2015 ENV concluded that outdoor applications with a scenario paints applied on window and door frames and doors was sufficient to carry out, because according the applicant tolylfluanid as PT7 was applied on wooden surfaces of window and door frames.

The WG concluded also that an indoor scenario is not needed, as the worst case is covered by the industrial application/outdoor use. Although painted or plastered surfaces indoors may be significant larger, emission from these materials are not expected as the majority

[2] Use Class 2: Situation in which the wood or wood-based product is under cover, fully protected from the weather but where occasional but not persistent wetting may occur.

Use Class 3: Situation in which the wood or wood-based product is not covered and not in contact with the ground. It is either continually exposed to the weather or is protected from the weather but subject to frequent wetting.

of these surfaces are not frequently wetted. Emission indoors is only expected in the wet area of bathrooms during shower events. Considering that the surface directly exposed to water (4 m²) is lower than surfaces outdoors (5.57 m²) and risks are absent for the latter, no risks for indoor applications are expected either.

In addition, tolylfluanid based paint is solvent based and used equipment is therefore not rinsed.

For the envisaged fields of use for tolylfluanid products the following uses and scenarios have been addressed (Table 11).

Table 11. Relevant exposure scenarios for use of tolylfluanid in coatings on wood

Main exposure scenario	Subcategory
Industrial application	- Dipping wooden articles - Automated spraying
Industrial storage	- Dipping wooden articles - Automated spraying
***In situ* brush application by amateur and professional users**	Bridge over pond - Fence (poles with leachable planks between; 2 m high, 1 m long) - Timber or cladded house (height 2.5 m, circumference is 50 m)
In-service leaching from treated wood	- Bridge over pond (as above) - Fence (as above) - Timber or cladded house (as above) - Noise barrier (poles with leachable planks in between; 3 m high, 1000 m long)
City scenario: outdoor applications	- Paints applied on window and doors frames and doors in service and application phase
Direct emission to surface water in urban areas	- Bypass of STP - Direct rainwater discharge

Leaching asessment

The leaching of tolylfluanid was studied under natural weather conditions on a field test site at the Danish Technological Institute in Taastrup near Copenhagen (Klamer, Christensen and Morsing 2008). Wooden panels were first brushed with a primer (Guide recipe JJT 3850) containing 0.70% (w/w) tolylfluanid to obtain a final amount of 1400 mg a.i./m^2 wood. Subsequently a top coat (GORI 88 from Dyrup) containing 0.45% (w/w) a.i. was applied to obtain a final amount of 1125 mg a.i./m^2 wood. After the treatment the test set-ups were exposed to natural rainfall. The leaching experiment was conducted over five different time periods (see Table 12).

Table 12. Leaching values for tolylfluanid from a field study under natural weather conditions (Klamer and Morsing, 2008) for an applied amount of in total 2525 mg a.i./m^2 wood (1400 mg a.i./m^2 applied as a primer and 1125 mg a.i./m^2 wood applied as a final top coat). Experiment contains the original test of 53 days with continuous collection of water and four additional separate sampling periods

	Days since start	Water collection from the beginning of each sampling period	Accumulated amount of rain	Concentration of tolylfluanid in leachate	FLUX (Δt)
		days	mm	mg/m^2 exposed wood	mg/m^2/day
The original study 25.10. - 16.12.2006					
25.10. 2006	1	-	-	-	-
27.10. 2006	2	2	5	0.14	0.07
1.11. 2006	7	7	18	0.52	0.07
9.11. 2006	16	16	45	0.99	0.06
16.11. 2006	23	23	62	1.55	0.07
16.12. 2006	53	53	95	5.65	0.11
Additional four separate sampling periods in order to calculate FLUX					
Sampling period 7. -29.5. 2007					
7.5. 2007	195	-	-	-	-
29.5.2007	217	22	69	0.54	0.02
Sampling period 2.9. - 1.10. 2007					
2.9. 2007	313	-	-	-	-
1.10. 2007	342	29	46	1.65	0.08
Sampling period 14.11. - 10.12. 2007					
14.11.2007	386	-	-	-	0
10.12.2007	413	26	44	0.44	0.02
Sampling period 1.4. - 27.5. 2008					
1.4.2008	525	-	-	-	-
27.5.2008	580	57	57	0.072	0.02* (0.01)

The leaching study can be regarded as a worst case scenario, because the collected leachate does not only contain tolylfluanid released from the top coat but also tolylfluanid released from the primer below. This was demonstrated in another variant of the leaching study in which the wooden panels treated tolylfluanid as a primer JJT 3580 were treated with a top coat (GORI 88 from Dyrup) without tolylfluanid. Thereby leaching rates between 0.01 and 0.05 mg tolylfluanid/m^2 exposed wood/day could be determined.

For the different scenarios the following leaching rates were applied:

The first sampling period relatively constant leaching rates between 0.06 and 0.11 mg tolylfluanid/m^2 exposed wood/day with a slight increase towards the end of the period were determined. For the storage assessment and the **TIME 1** risk assessment the leaching rate of **0.19 mg/m^2/d** was derived by divided the cumulative amount of tolylfluanid of 5.65 mg/m^2 during the first sampling period by 30 days (5.65mg/m^2/30=0.19). Leaching rate of 0.19 mg/m^2/day can be regarded as a worst case because it exceeds each of the determined leaching rates of the first sampling period considerably.

For TIME 2 (service life of 5 or 15 years) an average leaching rate during the whole study period of **0.06 mg/m^2/day** was derived.

The exposure calculations were carried out on the basis of an applied amount of 1500 mg tolylfluanid/m^2 treated wood, because the maximum likely content of tolylfluanid in coatings is 1400 mg/m^2 (see Table 3.1.2 Intented use). Thus, the leaching values obtained from the top coat leaching test with applied amount of 1125 mg/m^2 were corrected to correspond the retention of 1500 mg/m^2 and corrected and multiplied by the factor of 1.333 (1500/1125=1.333).

The following leaching rates (Table 13) were used in exposure calculations for the applied amount of 1500 mg tolyfluanid/m^2 (retention) in top coat application. It should be born in mind that these leaching values include also possible tolylfluanid leaching from the primer, because the top coat was applied on wood treated with the primer. Thus, values can be considered as worst case values.

Table 13. Leaching rates of tolyfluanid used in the risk assessment

	Daily flux
Time 1 (15 days and 30 days)	0.253 mg/m^2/d
Time 2 (1825 days and 5475 days)	0.080 mg/m^2/d

Leaching rates for DMST and N,N-DMS for PEC calculations were calculated from tolylfluanid leaching rates by taken into account the difference in molecular weight, i.e. for DMST tolylfluanid leaching rates were multiplied with 0.617 and for N,N-DMS with 0.356. This is a worst case calculation because %-formation of the degradation products in degradation studies was not taken into account.

Table 14. Leaching rates for DMST and N,N-DMS used in the risk assessment

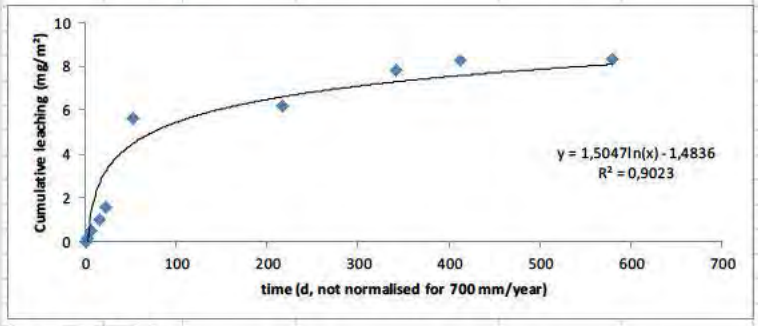
		Daily flux mg/m^2/d
DMST	Time 1 (15 days and 30 days)	0.156
	Time 2 (1825 days and 5475 days)	0.049

N,N-DMS	Time 1 (15 days and 30 days)	0.090
	Time 2 (1825 days and 5475 days)	0.029

Acceptability of the above mentioned leaching test and especially derivation of TIME 2 was debated because rainfall was not monitored continuously over the whole study period, but only over the period over which leachate was collected. Based on the comments received on the leaching test from OMS it was questionable if TIME2 was possible to derive at all. Finally, it was concluded at the WGIV 2015 that the leaching test as well as the leaching rates derived by eCA can be used for risk assessment because they are worst case values. The Netherlands provided calculations below which actually show that leaching rates of tolylfluanid could be lower than the ones currently used in the risk assessment. The leaching rate for TIME 1 proposed by the Netherlands was **0.048 mg/m²/d** (1.55 mg/m² / 32.3 (days normalised for 700 mm/year). For TIME 2 **0.04 mg/m²/d** calculated from day 30 to day 56 and normalised for 700 mm rainfall/year or **0.005 mg/m²/d** extrapolated Qleach2 by plotting cumulative leaching against the number of day (not normalised) by using a logarithmic curve (Qleach=a*ln(t)+b). After 1825 days the amount leached is 9.82 mg/m² corresponding 0.005mg/m²/d. Nevertheless, it was noticed that these leaching rates will not affect the final outcomes due to possible formation of NDMA in surface water and groundwater after ozonation process.

Cummulative

days	mm	days norm.	leaching over period (mg/	m.leaching (mg/m²)				
1	0	0,0		0,00001				
2	5	2,6		0,14				
7	18	9,4		0,52				
16	45	23,5		0,99				
23	62	32,3		1,55	Proposed value for Qleach1 (mg/m²)	rate:	0,047945	mg/m²/d
53	95	49,5		5,65				
217	no data	#ARVO!	0,54	6,19				
342	no data	#ARVO!	1,65	7,84				
413	no data	#ARVO!	0,44	8,28				
580	no data	#ARVO!	0,072	8,35				



Per sampling period

interval (d)	mm	days norm.	mg/m²	rate (mg/m²/d)				
2	5	2,6	0,14	0,05				
5	18	9,4	0,38	0,04				
9	45	23,5	0,47	0,02		a	1,5047	
7	62	32,3	0,56	0,02		b	-1,4836	
30	95	49,5	4,1	0,08		time	Qleach1	
22	69	36,0	0,54	0,02		30	3,634182	mg/m²
29	46	24,0	1,65	0,07		1825	9,815697	mg/m²
26	44	22,9	0,44	0,02				
57	57	29,7	0,72	0,02				
			average	0,04	mg/m²/d	calculated over the green cells		
			Qleach2	75,37975926	mg/m²			

If these new leaching rates were used in the risk assessment they should be multiplied with 1.333 in order to be comparable with the leaching values (in Tables 3.3-4. and 3.3-5) used in the risk assessment. Consequently, new leaching rates would be for Time 1: 0.064 mg/m2/d (=0.048 x 1.333), Time 2: 0.053 mg/m2/d (=0.04 x 1.33) and Time 2: 0.007 mg/m2/d (= 0.005 x 1.333). These leaching rates were not, however, used in the current risk assessment, because the values calculated by eCA can be considered as worst case.

PECs calculations

All tolylfluanid PEC calculations are based on an application rate of 1.5 g tolylfluanid/m^2 for spraying or brushing treatments and 123 g tolylfluanid/m^3 for the dipping treatment and automated spraying. For degradation products the difference in molecular weight of DMST and N,N-DMS compared to tolylfluanid were taken into account and application rates of tolylfluanid were multiplied with 0.617 and 0.356 in order to get application rates for DMST and N,N-DMS, respectively. DMST and N,N-DMS are major degradation products of tolylfluanid. No PECs were calculated for intermediate degradation product DMST-acid, because its possible risk can be considered to be taken into account already with DMST assessment.

On the basis of log Kow (3.9) and log Koc (3.35) tolylfluanid fulfils the trigger value for sediment risk assessment in the TGD and could partition to the sediment. Partition to sediment was not, however, detected at all in the [N-methyl-^{14}C]-tolylfluanid water/sediment key study (Sneikus 2007), where all degradation products were detected and identified. Thus, no dissipation rate constant for tolylfluanid could be derived. Due to the rapid primary degradation and absence of partition to the sediment in the water/sediment study sediment is not considered as a compartment of highly concern for tolylfluanid. TMIII 2011 agreed that sediment risk assessment is not needed for active substances which degrade rapidly and do not partition to sediment. TMII 2013 decided that sediment risk assessment is not needed for tolylfluanid as antifouling substance and surface water risk assessment was considered protective enough for sediment dwellers because unacceptable risk was already detected in the water and RMMs were considered. Besides, sediment risk assessment based on PNEC derived from equilibrium partition method in the lack of sediment organisms study would have given the same results as surface water risk assessment. Thus, regarding tolylfluanid as PT7 substance sediment exposure can be considered even more negligible and therefore the assessment was not carried out. Sediment risk assessment was not trigger for degradation products. Log Kow and log Koc of DMST are 1.99 and 1.97, respectively. Log Kow of N,N-DMS is -0.8 and log Koc was not possible to determine because there were no adsorption at all. Besides, there are no sediment organisms study for N,N-DMS.

The following degradation half-lives and rate constants were used in exposure calculations of tolylfluanid, DMST and N,N-DMS in water and soil (Table 15).

Table 15. Degradation half-lives and rate constants of tolylfluanid, DMST and N,N-DMS in relevant environmental temperature used in the risk assessment in water and soil

Compound	Temperature	Water and STP		Soil	
	°C	DT50 (d) water/sediment degradation System	k (d/1)	DT50 (d)	k (d/1)
Tolylfluanid	12	0.6	1.22	1.5	0.46
DMST	12	91.03	0.0076	5.5	0.13
N,N-DMS	12	>1896	>0.000366	1325	>0.000523

2.2.2.6 RISK CHARACTERISATION FOR THE ENVIRONMENT

Sewage treatment plant (STP)

Tolylfluanid and DMST do not cause unacceptable risk to microbes in the STP (Table 16). STP risk assessment has not been carried out for N,N-DMS due to lack of $PNEC_{STP}$.

Table 16. PEC/PNEC-ratios of tolylfluanid and DMST resulting from industrial application and in-service leaching emissions to a local sewage treatment plant (STP)

SCENARIO		Tolylfluanid			DMST		
		PEC_{stp} (µg/L)	$PNEC_{stp}$ (µg/L)	PEC/PNEC	PEC_{stp} (µg/L)	$PNEC_{stp}$	PEC/PNEC
Dipping		9.07	1000	0.009	111	14300	0.008
Automated spraying	Small plant	2.21		0.002	27.4		0.0019
	Large plant	22.1		0.022	274		0.0192
Noise Barrier	30 days	0.13		<0.001	0.161		<0.001
	15 years	0.04		<0.001	0.051		<0.001

Aquatic compartment

Unacceptable risk to surface water organisms from industrial dipping and automated spraying applications of paints containing tolylfluanid as a film preservative from large plant are not very likely due to the fact that industrial plants, in general, do not have direct connection to the STP and residues from industrial uses are to be recovered and treated as hazardous waste (Table 17).

Unacceptable risk of tolylfluanid to aquatic organisms from bridge over pond scenario during application *in situ* phase at day 1 can be considered transient, because no risk was identified after 30 days and 5 years (Table 17). Tolylfluanid is rapidly degraded in water.

DMST and N,N-DMS do not cause unacceptable risk to aquatic organisms in any of the scenarios (Table 18, Table 19).

Table 17. PEC/PNEC ratios of tolylfluanid in surface water

SCENARIO				PEC surface water (µg/L)	PNEC surface water (µg/L)	PEC/PNEC
Dipping	Application via STP *			0.907	0.265	**3.423**
	Storage			0.013		0.049
Automated spraying	Application via STP *	Small plant		0.221		0.834
		Large plant		2.21		**8.340**
	Storage	Small plant		0.002		0.008
		Large plant		0.015		0.057
Noise Barrier	Leaching in-service via STP after dipping or automated spraying *		30 days	0.013		0.049
			15 years	0.004		0.015
Bridge over pond	Application *in situ* *	Professional	1 day	0.45		**1.698**
		Amateur	1 day	0.75		**2.830**
	Application *in situ* + in-service leaching	Professional	30 days	0.014		0.053
			5 years	0.001		0.004
		Amateur	30 days	0.023		0.087
			5 years	0.001		0.004
	Leaching in service after brushing		30 days	0.002		0.008
			5 years	0.001		0.004
	Leaching in service after dipping or spraying		30 days	0.002		0.008
			15 years	0.001		0.004

* No degradation taken into account.
Grey color indicates unacceptable risk.

Table 18. PEC/PNEC ratios of DMST in surface water

SCENARIO				PEC surface water (µg/L)	PNEC surface water (µg/L)	PEC/PNEC
Dipping	Application via STP *			11.1	140	0.080
	Storage			0.012		<0.001
Automated spraying	Application via STP *	Small plant		2.74		0.020
		Large plant		27.4		0.206
	Storage	Small plant		0.0013		<0.001
		Large plant		0.013		<0.001
Noise Barrier	Leaching in-service via STP after dipping or automated spraying *		30 days	0.016		<0.001
			15 years	0.005		<0.001
Bridge over Pond	Application *in situ* *	Professional	1 day	0.28		0.002
		Amateur	1 day	0.46		0.003
	Application *in situ* + in-service leaching	Professional	30 days	0.270		0.002
			5 years	0.080		<0.001
		Amateur	30 days	0.435		0.003
			5 years	0.093		<0.001
	Leaching in service after brushing		30 days	0.022		<0.001
			5 years	0.060		<0.001
	Leaching in service after dipping or spraying		30 days	0.022		<0.001
			15 years	0.063		<0.001

* No degradation taken into account

Table 19. PEC/PNEC ratios of N,N-DMS in surface water

SCENARIO				PEC surface water (µg/L)	PNEC surface water (µg/L)	PEC/PNEC
Dipping	Application via STP *			6.56	10 000	<0.001
	Storage			0.007		<0.001
Automated spraying	Application via STP *	Small plant		1.620		<0.001
		Large plant		16.20		<0.001
	Storage	Small plant		0.0008		<0.001
		Large plant		0.008		<0.001
Noise Barrier	Leaching in-service via STP after dipping or automated spraying *		30 days	0.0095		<0.001
			15 years	0.003		<0.001
Bridge over pond	Application *in situ* *	Professional	1 day	0.160		<0.001
		Amateur	1 day	0.267		<0.001
	Application *in situ* + in-service leaching	Professional	30 days	0.172		<0.001
			5 years	0.330		<0.001
		Amateur	30 days	0.279		<0.001
			5 years	0.408		<0.001
	Leaching in service after brushing		30 days	0.014		<0.001
			5 years	0.213		<0.001
	Leaching in service after dipping or spraying		30 days	0.014		<0.001
			15 years	0.045		<0.001

* No degradation taken into account

Unacceptable risk to aquatic organisms from combined assessment when storage and industrial dipping and automated spraying applications of paints containing tolylfluanid as a film preservative from large plant are summed up are not very likely due to the fact that industrial plants, in general, do not have direct connection to the STP and residues from industrial uses are to be recovered and treated as hazardous waste (Table 20).

DMST and N,N-DMS do not cause unacceptable risk to aquatic organisms from combined emissions (Table 21, Table 22).

Table 20. Combined PEC/PNEC ratios of tolylfluanid in surface water

SCENARIO		PEC Surface water (µg/L)	PNEC surface water (µg/L)	PEC/PNEC
Dipping	Application [1] + Storage [2]	0.92	0.265	**3.48**
Automated spraying	Application [1] + Storage [2] (small plant)	0.223		0.84
	Application [1] + Storage [2] (large plant)	2.225		**8.40**

[1] No degradation taken into account
[2] Degradation in the whole water/sediment system taken into account (DT50 of 0.6 days)
Grey color indicates unacceptable risk.

Table 21. Combined PEC/PNEC ratios of DMST in surface water

SCENARIO		PEC surface water (µg/L)	PEC surface water (µg/L)	PEC/PNEC
Dipping	Application [1] + Storage [2]	11.11	140	0.080
Automated spraying	Application [1] + Storage [2] (small plant)	2.741		0.020
	Application [1] + Storage [2] (large plant)	27.41		0.200

[1] No degradation taken into account
[2] Degradation in the whole water/sediment system taken into account (DT50 of 91.03 days)

Table 22. Combined PEC/PNEC ratios of N,N-DMS in surface water

SCENARIO		PEC surface water (µg/L)	PEC surface water (µg/L)	PEC/PNEC
Dipping	Application [1] + Storage [2]	6.56	10000	<0.001
Automated spraying	Application [1] + Storage [2] (small plant)	1.620		<0.001
	Application [1] + Storage [2] (large plant)	16.208		<0.001

[1] No degradation taken into account
[2] Degradation in the whole water/sediment system taken into account (DT50 of >1896 days)

Sediment risk assessment was not carried out for tolylfluanid because it was not partitioning into the sediment in the water/sediment study. Besides, there is no sediment organisms study available and based on PNEC derived from equilibrium partition method PEC/PNEC ratios in sediment would give the same results as surface water risk assessment. Thus, surface water assessment can be considered protective enough also for sediment organisms.

Sediment risk assessment was not carried either for degradation products due to their low log Kow and Koc (DMST: log Kow=1.99 and log Koc=1.97, N,N-DMS: log Kow = -0.8 and log Koc was not possible to determine because there were no adsorption at all). Both products are also highly water soluble which indicate that sediment is not the compartment of concern. Besides, risk characterisation for surface water of DMST and N,N-DMS shown in the previous chapter clearly indicate that degradation products do not cause concern for aquatic organisms in surface water.

Terrestrial compartment

Unacceptable risk of tolylfluanid to soil organisms after in situ application of house and fence at day 1 can be considered transient, because no risk was identified after 30 days and 5 years. Tolylfluanid is rapidly degraded in soil (Table 23). No risk to soil organisms was detected in other scenarios.

DMST causes unacceptable risk to soil organisms only *in situ* application by amateurs at day 1 from the house scenario, but no risk was identified after 30 days and 5 years (Table 24).

Unacceptable risk of N,N-DMS to soil organisms identified only after 20 years of storage after dipping and automated spraying is not very likely either, because wood coated with paints containing tolylfluanid as a film preservative is not generally stored outside (Table 25).

Table 23. PEC/PNEC ratios of tolylfluanid in soil

Scenario				PEC_{soil} (mg/kg wwt)	$PNEC_{soil}$ (mg/kg wwt)	PEC/PNEC
Dipping	Storage		30 days	0.0033	0.076	0.043
			20years	0.0035		0.046
Automated spraying	Storage		30 days	0.0033		0.043
			20years	0.0035		0.046
Fence	Application *in situ**	Professional	1 day	0.2117		**7.059**
		Amateur	1 day	0.3529		**11.77**
	Application *in situ* + leaching in service	Professional	30 days	0.0177		0.233
			5 years	0.0011		0.014
		Amateur	30 days	0.0279		0.367
			5 years	0.0012		0.016
	Leaching in service after brushing		30 days	0.0023		0.030
			5 years	0.0008		0.012
	Leaching in service after dipping or spraying		30 days	0.0024		0.032
			15 years	0.0008		0.012
House	Application *in situ**	Professional	1 day	0.2647		**8.824**
		Amateur	1 day	0.4412		**14.71**
	Application *in situ* + leaching in service	Professional	30 days	0.0221		0.291
			5 years	0.001		0.013
		Amateur	30 days	0.0348		0.458
			5 years	0.0015		0.020
	Leaching in service after brushing		30 days	0.0030		0.039
			5 years	0.0010		0.013
	Leaching in service after dipping or spraying		30 days	0.0030		0.039
			15 years	0.0010		0.013
Noise Barrier	Leaching in service after dipping or spraying		30 days	0.0003		0.004
			15 years	0.0001		0.001

* Degradation in soil not taken into account

Grey color indicates unacceptable risk.

Table 24. PEC/PNEC ratios of DMST in soil

Scenario				PEC_{soil} (mg/kg wwt)	$PNEC_{soil}$ (mg/kg wwt)	PEC/PNEC
Dipping	Storage		30 days	0.0059	0.196	0.030
			20years	0.0080		0.041
Automated spraying	Storage		30 days	0.0060		0.031
			20 years	0.0080		0.041
Fence	Application *in situ**	Professional	1 day	0.1307		0.594
		Amateur	1 day	0.2178		0.990
	Application *in situ* + leaching in service	Professional	30 days	0.0381		0.194
			5 years	0.0024		0.012
		Amateur	30 days	0.061		0.311
			5 years	0.0028		0.014
	Leaching in service after brushing		30 days	0.0043		0.022
			5 years	0.0018		0.009
	Leaching in service after dipping or spraying		30 days	0.0043		0.022
			15 years	0.0018		0.009
House	Application *in situ**	Professional	1 day	0.1633		0.833
		Amateur	1 day	0.2722		**1.389**
	Application *in situ* + leaching in service	Professional	30 days	0.0476		0.243
			5 years	0.0030		0.015
		Amateur	30 days	0.0758		0.287
			5 years	0.0035		0.018
	Leaching in service after brushing		30 days	0.0054		0.028
			5 years	0.0023		0.012
	Leaching in service after dipping or spraying		30 days	0.0054		0.028
			15 years	0.0023		0.012
Noise Barrier	Leaching in service after dipping or spraying		30 days	0.0006		0.003
			15 years	0.0002		0.001

*Degradation in soil not taken into account

Grey color indicates unacceptable risk.

Table 25. PEC/PNEC ratios of N,N-DMS in soil

Scenario				PEC_{soil} (mg/kg wwt)	$PNEC_{soil}$ (mg/kg wwt)	PEC/PNEC
Dipping	Storage		30 days	0.0088	0.3	0.029
			20years	0.8282		**2.761**
Automated spraying	Storage		30 days	0.0088		0.029
			20years	0.8282		**2.761**
Fence	Application *in situ**	Professional	1 day	0.0753		0.251
		Amateur	1 day	0.1259		0.420
	Application *in situ* + leaching in service	Professional	30 days	0.0811		0.270
			5 years	0.1407		0.469
		Amateur	30 days	0.1313		0.438
			5 years	0.1733		0.578
	Leaching in service after brushing		30 days	0.0064		0.021
			5 years	0.0922		0.307
	Leaching in service after dipping or spraying		30 days	0.0064		0.021
			15 years	0.1738		0.579
House	Application *in situ**	Professional	1 day	0.0941		0.314
		Amateur	1 day	0.1567		0.522
	Application *in situ* + leaching in service	Professional	30 days	0.1014		0.338
			5 years	0.1759		0.586
		Amateur	30 days	0.1635		0.545
			5 years	0.2162		0.721
	Leaching in service after brushing		30 days	0.0080		0.027
			5 years	0.1152		0.384
	Leaching in service after dipping or spraying		30 days	0.0080		0.027
			15 years	0.2173		0.724
Noise Barrier	Leaching in service after dipping or spraying		30 days	0.0009		0.003
			15 years	0.0235		0.0781

*Degradation in soil not taken into account

Grey color indicates unacceptable risk.

Groundwater

Risks to groundwater were assessed only for N,N-DMS, which is a very mobile and persistent metabolite (Table 26). The groundwater concentrations of N,N-DMS exceed the drinking water standard of 0.1 µg/l (Drinking water directive 98/83/EC4) as well as groundwater quality standard of 0.1 µg/l (Groundwater directive 118/2006/EC5) in eight of the nine Focus scenarios. In addition, calculated theoretical NDMA concentrations are also high and exceed the specific health based value (HBV) of 0.1 µg/l set for NDMA by the WHO and established intervention limit values of certain cities and countries, e.g. 10 ng/l (California), 9 ng/l (Ontario), 10 ng/l (Germany, UBA). Waters with concentrations higher that 200 ng/l are forbidden to be used as drinking water in California. Although groundwater is seldom ozonated as such, ozone can be used for removing impurities from raw water, also in groundwater. In small municipalities, where surface water and groundwater are mixed, ozonation can take place after mixing (Table 27).

Table 26. Maximum concentrations of N,N-DMS (µg/l) in the groundwater based on different leaching

Scenarios	17 houses/ha Modelled using FOCUS PEARL 3.3.3	16 houses /ha Estimated using simple linear correction factor + $F_{weather}$ = 0.5		
	Primer retention (1400 mg/m²) 0.767 mg/m²/d	Primer retention (1400 mg/m²) 0.767 mg/m²/d	Primer+ Top coat TIME 1 0.253 mg/m²/d	Primer+ Top coat TIME 2 0.080 mg/m²/ d
CHATEAUDUN	10.086	4.75	1.57	0.49
HAMBURG	10.677	5.02	1.65	0.52
JOKIOINEN	14.827	6.98	2.30	0.73
KREMSMUENSTER	10.610	5.00	1.65	0.52
OKEHAMPTON	6.981	3.29	1.08	0.34
PIACENZA	8.106	3.81	1.25	0.40
PORTO	4.996	2.35	0.77	0.24
SEVILLA	1.789	0.84	0.28	0.09
THIVA	4.545	2.14	0.70	0.22

Grey color indicates that groundwater limit value of 0.1 µg/l is exceeded.

Table 27. Maximum concentrations of NDMA (µg/l) assuming ozonation of water with N,N-dimethylsulfamide concentrations from the Table above (NDMA from N,N-DMS was calculated by using the maximum transformation efficiency of 32 % in units of µg or µg/l).

Scenarios	16 houses /ha Estimated using simple linear correction factor + $F_{weather}$ = 0.5		
	Primer only retention (1400 mg/m²) 0.767 mg/m²/d	Primer + Top coat TIME 1 0.253 mg/m²/d	Primer + Top coat TIME 2 0.080 mg/m²/d
CHATEAUDUN	1.52	0.50	0.16
HAMBURG	1.61	0.53	0.17
JOKIOINEN	2.23	0.74	0.23
KREMSMUENSTER	1.60	0.53	0.17
OKEHAMPTON	1.05	0.34	0.11
PIACENZA	1.22	0.40	0.13
PORTO	0.75	0.25	0.08
SEVILLA	0.27	0.09	0.03
THIVA	0.68	0.22	0.07

Grey color indicates that WHO limit value of µg/l is exceeded.

Therefore, groundwater pollution cannot be excluded. No appropriate risk mitigation methods are available as seen in the chapters below:

Water purification measures

According to the applicant (Klamroth et al. 2007) ozone is used for purification of water often in combination with other steps in water treatment. These steps, e.g. activated carbon filtering or sand filtering following ozonation, can lead into direct reduction of the level of NDMA in water in optimal conditions. In addition, reducing the level of N,N-dimethylsulfamide, the precursor of NDMA, in water by ion exchange resins or by other oxidation methods were reported to be possible ways to reduce the concentration of NDMA in water. According to the participant (Schmidt 2007) efficacy of several oxidation methods in removal of N,N-dimethylsulfamide from drinking water exceeded 85 %. However, the practicality and acceptability of these methods by waterworks remain uncertain. The high solubility in water of NDMA may hinder applicability of carbon filtering. The participant (Klamroth et al 2007) has referred to experiences where use of biologically active filters (sand filters or biologically active activated carbon filters) have been proposed to be effective in removing of NDMA from raw water in the Netherlands and in the UK, even though findings on considerable variability of effectiveness of NDMA removal by biodegradation was mentioned, too. The participant's report on the monitoring in the UK does not contain information on the transformation efficiency by ozone or on efficacy of reduction of levels of N,N-dimethylsulfamide in water purification process. The RMS has not been able to receive information from other sources to confirm the effectiveness of biological degradation of NDMA in activated carbon. A reduction in levels of NDMA could be explained by biological activity in carbon filters. Other purification mechanisms with poorly characterised properties in multistep purification processes are regarded possible.

Replacement of ozonation with treatment with other oxidants or disinfectants, as well as moderation of the ozonation process has been proposed by the participant as additional controlling measures. However, the RMS is not convinced if such approaches are sufficient or are seen practical by water authorities. The stability and the high mobility of N,N-dimethylsulfamide make it a candidate for a long-lasting impurity in both surface water and groundwater.

Due to the stability of N,N-dimethylsulfamide in water it can accumulate in sources of drinking water, which makes it a substance that should be regarded with a concern. The further technical development of water purification technology will remain an open question. The extent of use of ozone in future is unknown.

It should be borne in mind that Biocide regulation regulates making available on the market and use of biocidal products. Thus, risk mitigation should therefore consist of measures directly linked to that not to practices or techniques in waterworks.

Prohibition for use of tolylfluanid coatings on wood in groundwater protection areas

Prohibition of use of tolylfluanid film preservatives in groundwater protection areas has been considered as one possible risk mitigation method. However, regional or European wide prohibition does not seem feasible. The concept of groundwater protection area does not exist in all European countries or it is not similar in different MS. Users of biocidal products or treated timber do not necessarily know if the place is situated on such an area. Therefore, this type of prohibition is impossible to enforce.

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. Therefore, likely concentrations of tolylfluanid, DMST and N,N-DMS in air are not considered to be of significant concern for this Product Type and proposed use patterns.

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.

Biota (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.

City scenario and direct discharge to surface water

Table 28. PEC/PNEC in STP, surface water via STP, soil and concentrations in pore water and potential maximum concentration of NDMA from service life use of City scenario, i.e. paint applied on window and door frames and doors

	STP			Surface water			Agricultural soil			Pore water	NDMA
Substance E_{local} (kg/d)	**PEC (µg/l)**	**PNEC (µg/l)**	**PEC/ PNEC**	**PEC (µg/l)**	**PNEC (µg/l)**	**PEC/ PNEC**	**PEC (µg/kg ww)**	**PNEC (µg/kg ww)**	**PEC/ PNEC**	**PEC (µg/l)**	**(µg/l)**
Tolylfluanid 0.0017825	0.437	1000	<0.001	0.0437	0.265	0.155	1.03	76	0.014	0.0221	-
DMST 0.0010919	0.536	14300	<0.001	0.0536	140	<0.001	0.118	196	<0.01	0.053	-
N,N-DMS 0.0006462	0.323	-	-	0.0323	10000	<0.001	0.0006	300	<0.01	0.0019	<0.001

Table 29. PEC/PNEC in STP, surface water via STP, soil and concentrations in pore water and potential maximum concentration of NDMA from application phase of city scenario, i.e. paint applied on window and door frames and doors (Only non-professional application was calculated for DMST and N,N-DMS, because it is worst case)

	STP			Surface water			Agricultural soil			Pore water	NDMA
Substance Elocal (kg/d)	**PEC (µg/l)**	**PNEC (µg/l)**	**PEC/ PNEC**	**PEC (µg/l)**	**PNEC (µg/l)**	**PEC/ PNEC**	**PEC_l (µg/kg ww)**	**PNEC (µg/kg ww)**	**PEC/ PNEC**	**PEC (µg/l)**	**(µg/l)**
Tolylfluanid 0.00263 np.	0.645	1000	<0.001	0.0645	0.265	0.243	1.53	76	0.020	0.0326	-
0.001579pr.	0.387		<0.001	0.0386		0.146	0.916		0.012	0.0196	-
DMST 0.00162 np.	0.795	14300		0.0795	140		0.176	196	<0.001	0.0789	-
N,N-DMS 0.00094 np.	0.47	-	-	0.047	10000	<0.001	0.0008	300	<0.001	0.0027	<0.002

np.= non professionals

pr=professionals

Tolylfluanid or degradation products do not cause unacceptable risk to STP, aquatic or soil organisms from service life (Table 28) and application phase (Table 29) from very restricted use as paints applied window and door frames and doors. No groundwater risk or elevated concentrations of NDMA are either calculated.

Table 30. PEC/PNEC in surface water and potential maximum concentrations of NDMA in surface water assuming ozonation of water containing N,N-DMS after bypass of STP

Scenario	Substance		E_{local} (kg/d)	Clocaleff µg/l	PEC µg/l	PNEC µg/l	PEC/PNEC	NDMA µg/l
Normal service life 4000 houses treated	Tolylfluanid		0.0017825	0.891	0.0888	0.265	0.335	-
	DMST		0.0010919	0.546	0.0545	140	<0.001	-
	N,N-DMS		0.000646	0.323	0.0323	10000	<0.001	0.010
Application	Tolylfluanid	non-professionals	0.00263	1.31	0.131	0.265	0.494	-
		professionals	0.001579	0.79	0.079		0.298	-
	DMST (non-profesionals)		0.00162	0.81	0.081	140	<0.001	-
	N,N-DMS (non-profess.)		0.00094	0.47	0.047	10000	<0.001	0.015

Tolylfluanid or degradation products do not cause unacceptable risk to aquatic organisms from service life or application phase from restricted use as paints applied window and door frames and doors after bypass of STP (Table 30). Theoretical NDMA concentrations are not elevated either (Table 30).

Table 31. PEC/PNEC in surface water and potential maximum concentrations of NDMA in surface water assuming ozonation of water containing N,N-DMS after direct rainwater discharge to surface water

Scenario	Substance	E_{local} (kg/d)	Clocaleff µg/l	PEC µg/l	PNEC µg/l	PEC/PNEC	NDMA
Normal service life 4000 houses treated	Tolylfluanid	0.0017825	2.97	0.297	0.265	1.121	-
	DMST	0.00109	1.82	0.182	140	0.001	-
	N,N-DMS	0.000646	1.08	0.108	10000	<0.001	0.035
Application	Tolylfluanid	non-professionals	4.38	0.437	0.265	1.649	-
		professionals	2.63	0.263		0.991	-
	DMST	0.00162	2.7	0.27	140	0.002	-
	N,N-DMS	0.00094	1.57	0.157	10000	<0.001	0.050

Grey color indicates unacceptable risk

Tolylfluanid may cause unacceptable risk to aquatic organisms from service life (PEC/PNEC=1.2) and non-professional application phase (PEC/PNEC=1.6) when there is direct discharge to surface water after restricted use as paint applied window and doordoors frames and doors (Table 31). When taken into account, however, that the service life risk was calculated based on worst case leaching rates it can be concluded that the risk is minor. Regarding application phase risk mitigation method as protecting the painting area from spills can be needed for non-professionals.

DMST or N,N-DMS do not cause unacceptable risk to aquatic organisms. Theoretical NDMA concentrations are not elevated either regarding the WHO limit value of 0.1µg/l.

2.2.3 EXCLUSION CRITERIA AND CANDIDATES FOR SUBSTITUTION CRITERIA OF BPR (EU 528/2012)

Article 5 (exclusion criteria) of the Biocidal Products Regulation (BPR) states that an active substance cannot be approved if it: (1) is classified or meets the criteria for classification as CMR 1A or 1B in accordance with the CLP Regulations; (2) is considered to have endocrine disrupting properties; (3) or meets the criteria for PBT or vPvB according to Annex XIII to the REACH Regulation.

Available evidence at this time indicates that tolylfluanid does not meet these exclusion criteria as it is not classified or does not meet the criteria for classification as CMR 1A or 1B, does not have endocrine-disrupting properties and does not meet the criteria for PBT or vPvB.

Article 10 (candidates for substitution criteria) of the new BPR states that an active substance should be considered a candidate for substitution if:

(a) it meets one of the exclusion criteria;

(b) it is classified or meets the criteria for classification as a respiratory sensitiser (Resp Sens. 1) under the CLP Regulation;

(c) its AEL and/or AEC values are significantly lower than those of the majority of approved active substances for the same product type and use scenario;

(d) it meets two of the criteria for PBT according to Annex XIII to the REACH Regulation;

(e) there are reasons for concern linked to the nature of the critical effects that in combination with the use patterns and amount used could still cause concern, such as high potential of risk to groundwater;

(f) it contains a significant proportion of non-active isomers or impurities.

Available evidence indicates that tolylfluanid does not meet any of the criteria (a-f) of Article 10 and so should not be considered a candidate for substitution at this time.

Appendix I: List of endpoints

Appendix II: List of intended uses

Appendix III: List of studies

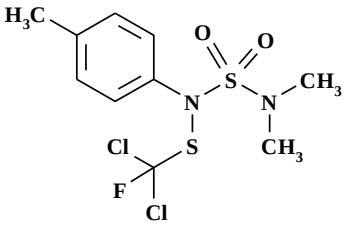
Appendix 1: List of endpoints

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	7

Identity

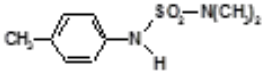
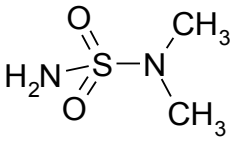
Chemical name (IUPAC)	N-(Dichlorofluoromethylthio)-N',N'-dimethyl-N-p-tolylsulfamide
Chemical name (CA)	Methanesulfenamide, 1,1-dichloro-N-[(dimethylamino)sulfonyl]-1-fluoro-N-(4-methylphenyl)-
CAS No	731-27-1
EC No	211-986-9
Other substance No.	CIPAC No. 275
Minimum purity of the active substance as 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/cm^3 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 x 10^{-4} Pa at 20°C (extrapolated); 4 x 10^{-4} Pa at 25°C (extrapolated) (purity: 99.9%)
Henry's law constant (Pa m^3 mol $^{-1}$)	6.6 × 10^{-2} Pa· m^3· 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 metabolites 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)
Spectral information	Information added, see Doc IIA	Information added, see Doc IIA

Classification and labelling of tolylfluanid according to Regulation (EC) No 1272/2008 (CLP regulation)

Table 32. Tolylfluanid containing < 0.1%(w/w) of particles with an aerodynamic diameter below 50µm (Index No 613-116-01-4) according to CLP Regulation.

Classification	
Hazard Class and Category Codes	Eye Irrit. 2 H319 STOT SE 3 H335 Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Acute 1 H400
Labelling	
Pictograms	GHS07, GHS09
Signal Word	Warning
Hazard Statement Codes	H319: Causes serious eye irritation. H335: May cause respiratory irritation. H315: Causes skin irritation. H317: May cause an allergic skin reaction H410:Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 10 (Aquatic acute 1)

Table 33. Tolylfluanid containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm (Index No 613-116-00-7) according to CLP Regulation.

Classification	
Hazard Class and Category Codes	Acute Tox. 2* H330 STOT RE 1** H372 Eye Irrit. 2 H319 STOT SE 3 H335 Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Acute 1 H400
Labelling	
Pictograms	GHS05, GHS09
Signal Word	Danger
Hazard Statement Codes	H330: Fatal if inhaled. H372: Causes damage to organs through prolonged or repeated exposure. H319: Causes serious eye irritation. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H410:Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 10 (Aquatic acute 1)

Regarding environment Aquatic Chronic 1 H410 with M=1 (Aquatic Chronic) classification is proposed according to Regulation (EC) No 286/2011. This is based on a NOEC of 0.00265 mg/l for *Daphnia magna.*

Chapter 2: Methods of Analysis

Analytical methods for the active substance

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.
Impurities in technical active substance (principle of method)	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)	The method is relevant for PT21. 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 tolylfluanid 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**.**
Rate and extent of the dermal adsorption for the representative product(s):	**25% dermal absorption** was used for the concentrated product (containing 47% of tolylfluanid), based on the irritant effects of the active substance and the presence of the solvent in the representative product. 15 % dermal absorption was used for the products containing 0.7-0.9% of tolylfluanid, 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 ± 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/m^3 (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	Rabbit / Embryo (teratogenicity): increased

effect	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	≥ 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;	
Production of end-use products, mixing and loading Model: TNsG Mixing and loading model 7 PPE: no RPE, gloves and coated coveralls (Tier 2)	Total systemic exposure: 0.027 mg/kg bw /day MOE : 670
Maintenance of production machines Model: Default values from BEAT - Cleaning of Spray Equipment PPE: Rinsing the system prior the maintenance work, gloves and coated coveralls (Tier 2)	Total systemic exposure: 0.046 mg/kg bw /day MOE : 390
Application: Industrial manual dipping Model: TNsG Handling Model 1 , solvent based product PPE: no PPE (Tier 1)	Total systemic exposure: 0.088 mg/kg bw /day MOE : 200
Application: Industrial mechanical dipping Model: TNsG Dipping Model 1, solvent based product PPE: Gloves and coated coveralls (Tier 2)	Total systemic exposure: 0.027 mg/kg bw /day MOE : 670
Cleaning out dipping tank Model: TNsG Handling Model 1, solvent based product PPE: no PPE (Tier 1)	Total systemic exposure: 0.018 mg/kg bw /day MOE : 1400
Application: Spraying (cleaning of a spray equipment added) Model: TNsG Spraying Model 3 and BEAT PPE: RPE, gloves and impermeable coveralls (Tier 2)	Time 360 min: Total systemic exposure: 0.095 mg/kg bw /day MOE : 190
Application: Brush application (cleaning of a brush added) Model: Worked example in BEAT (indoor decorative painting) PPE: gloves and coated coveralls (Tier 2)	Time 360 min: Total systemic exposure: 0.13 mg/kg bw /day MOE : 140
Handling treated wet wood Model: TNsG Handling Model 1 PPE: no (Tier 1)	Time one cycle (180 min): Total systemic exposure: 0.0046 mg/kg bw /day MOE : 3900
Primary exposure - non-professional use	
Brush and roller application (cleaning of a brush added) - indoors Model: TNsG Consumer product painting model 1, indoors No PPE (100% clothing penetration)	Total systemic exposure: 0.76 mg/kg bw /day MOE : 33
Brush and roller application (cleaning of a brush added) - outdoors Model: TNsG Brushing sheds and fences,	Total systemic exposure: 0.084 mg/kg bw /day MOE : 300

outdoors No PPE (100% clothing penetration)	
Secondary exposure	
Paint removal - professionals Paint removal by sanding Model: reverse reference scenario and based on calculations on dust amoutns, tolylfluanid concentration of the surface PPE: no PPE (Tier 1)	Total systemic exposure: 0.009 mg/kg bw /day MOE : 2800
Paint removal - non-professionals Paint removal by sanding Model: reverse reference scenario and based on calculations on dust amounts, tolylfluanid concentration of the surface PPE: no PPE (Tier 1)	Total systemic exposure: 0.046 mg/kg bw /day MOE : 160
Cleaning of working clothes (professionals) PPE: no PPE	Total systemic exposure: 0.11 mg/kg bw /day MOE : 160
Chronic inhlation exposure to evaporated residues (child)	negligible
Infant playing on coated wood sturtures and mouthing (chronic)	Total systemic exposure: 0.0035 mg/kg bw /day MOE : 5100
Infant schewing a wood off-cut (acute)	Total systemic exposure: 0.028 mg/kg bw /day MOE: 890
Toddler dermal contact wit wet paint (acute)	Total systemic exposure: 0.12 mg/kg bw /day MOE: 210
Infant contactin wet paint and mouthing (acute)	Total systemic exposure: 0.21 mg/kg bw /day MOE: 120

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)	Field of use envisaged for end-use product	In-use concentration for the a.s. in the end-product [% w/w]	Application amount of product in coating g/m2, (Content of a.s. in coating g/m2)	(m)
PT7 (Film preservative) to protect paint film coating on wooden surface met in UC2-3. The treatment of wood exclude any contact with feeds or foods.	EU	Preventol A 5-F	Fungi and mold	-	In-use concentration for the a.s. in the b.p. [% w/w] 44-47%	addition	-	-	Automated spraying (Industrial)	0.2-0.7	70-140 (0.2-1.0)	
									Dipping (Industrial/Professionals)	0.2-0.7	70-140 (0.2-1.0)	
									Spraying (Professionals)	0.2-0.7	70-140 (0.2-1.0)	
									Brushing (Professionals and amateurs)	0.2-0.9	70-180 (0.2-1.4)	
									Handling of treated wet wood (Professionals)	0.2-0.7	70-140 (0.2-1.0)	
									Cleaning out dipping tank after use (Professionals)	0.2-0.7	70-140 (0.2-1.0)	

*(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 studies

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
A3 A8	Bayer Chemicals AG	2003a	Preventol A5-S, Safety Data Sheet.	-	SDS No. 861298/08	No	Yes	No	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	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	05/00752	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	1400321075	Yes	No	Yes	LANXESS Deutschland GmbH
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	1466009 58	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
A3.1	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.; Kaussmann, M	2007a	Henry´s Law Constant of N,N-dimethylsulfamide	Bayer Ag	AF07/010		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
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

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	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
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	A93/0136/02 DOR	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
A3.6	Bogdoll, B.; Lemke, G.; Kaussmann, M	2007b	N,N-dimethylsulfamide - Determination of the dissociation constant (Titration Screening Method).	Bayer AG	AF07/017, Edition Number: M-284258-01-1		No	Yes	LANXESS Deutschland GmbH
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	14190510 07	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
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

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
A4.2	Brenneke, R.	1991	Residue analytical method, modification recoveries.	Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany	Az. 00086/M 014	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
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

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
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
A4.2	Riegner, K.	1992	Method for the determination of Tolylfluanid in air.	Bayer AG	0092	Yes	No	Yes	LANXESS Deutschland GmbH

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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
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 Freseniu s 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

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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
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
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

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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
A6	[redacted]	2007	KUE 13183B-N,N-dimethylsulfamid (Project: Tolylfluanid (KUE 13183B)) - Acute toxicity in the rat after oral administration.	[redacted]	AT03675,	Yes	No	Yyes	LANXESS Deutschland GmbH

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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 6357/07, 2006-02-06-	Yes-	No-	Yes-	LANXESS Deutschland GmbH
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

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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
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

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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
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
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

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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
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

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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
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

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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
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
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

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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
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

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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
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

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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
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 Mutagenizität sprüfung, 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
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

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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
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

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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
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

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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
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: Tolylfluanid) - 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

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A6.12.1	Andersson, L. (Bayer Sverige AB, Norway)	1994	Euparen M / Tolylfluanid.	-	LETTER (MO-00-002460)	No	No	Yes	LANXESS Deutschland GmbH
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
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

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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
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

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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
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

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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
A7.1.1.1.1	Erstling, K.	2001	Abiotic Degradation.	Bayer AG	G 01/0142/01 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	2005/0153/02	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 00/0153/00	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 00/0153/02	Yes	No	Yes	LANXESS Deutschland GmbH

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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
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

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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
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/97 O	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
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

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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
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

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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
A7.1.2.2.2.	Sneikus, J.	2007b	[N-methyl-14C]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

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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
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
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

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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
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

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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
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

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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
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

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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
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
A7.4.1.3	Anderson, J.P.E.	1995	Influence of Tolylfluanid on the Growth of the Green Alga, *Scenedesmus subspicatus*.	Bayer AG	AJO/133 495	Yes	No	Yes	LANXESS Deutschland GmbH

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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/158 097	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3	Caspers, N.	1997b	DMSA - Alga Growth Inhibition Test.	Bayer AG	689A/97 Al	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	3426121	Yes	No	Yes	LANXESS Deutschland GmbH
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

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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
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

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A7.4.2	[redacted]	1991	Tolylfluanid - Bioconcentration in Fish.	[redacted]	BF-007 (M 7747)	Yes	No	Yes	LANXESS Deutschland GmbH
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/166 497	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
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

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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
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

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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
A7.4.3.4	Hendel, B.	2001a	Influence of Tolylfluanid (tech.) on the Reproduction Rate of Water Fleas.	Bayer AG	HDB/rD m 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

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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
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/183198	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/183298	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/211 200	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/219 901	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/220 001	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/220 101	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. 000627BK)	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	TNW73863 (Project No. 000627BK)	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
A7.5.3.1.1	[redacted]	2000	TOLYLFLUANID techn. a.i.: Acute Oral Toxicity for Bobwhite Quail.	[redacted]	BAR/LD031	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

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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	-
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	-