FOREWORD INTRODUCTION

N,N-Dimethyldodecylamine

CAS N°: 112-18-5

SIDS Initial Assessment Report

For

SIAM 11

Orlando, United States, 23-26 January 2001

1. Chemical Name: N,N-Dimethyldodecylamine

2. CAS Number: 112-18-5

3. Sponsor Country: GERMANY
National SIDS Contact Point in Sponsor Country: Mr. Jan Ahlers

4. Shared Partnership with:

5. Roles/Responsibilities of the Partners:

- Name of industry sponsor /consortium
- Process used

6. Sponsorship History

- How was the chemical or category brought into the OECD HPV Chemicals Programme ?

SIDS Dossier and Testing Plan were reviewed at the SIDS Review Meeting in September 1993 where the following SIDS Testing Plan was agreed:

no testing ( )
testing (X)

Tests on water solubility, short-term toxicity with daphnia and algae, subchronic toxicity, and a screening test on reproduction/development toxicity have been conducted.
It was decided to perform the tests with the commercial mixture of dimethylalkylamines C12-16 containning 70 % C12 tert. Amine.
The assessment was discussed and agreed at SIAM 9 with the recommendation that an environmental risk assessment should be performed.
The post-SIDS SIAR with this risk assessment was discussed and agreed at SIAM 11.
After agreement of the assessment at SIAM 11, new plant toxicity tests became available. These data were included and the revised documents were approved via a written procedure.

7. Review Process Prior to the SIAM:

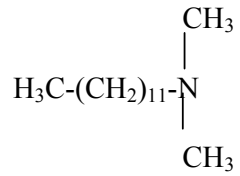
8. Quality check process:

9. Date of Submission:

10. Date of last Update:

11. Comments: The risk assessment covers both the pure substance as well as the commercial mixture with the CAS-No. 84649-84-3.

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	112-18-5
Chemical Name	N,N-Dimethyldodecylamine
Structural Formula	

RECOMMENDATIONS

The chemical is a candidate for further work.

SUMMARY CONCLUSIONS OF THE SIAR

There are two industrial products containing N,N-dimethyldodecylamine with different purities, Genamin 12R 302 D (> 95 % C12-Dimethyldodecylamine) and the structural related Genamin 302 D (approximately 70 % C12-, 25 % C12-14- and 5 % C16-dimethylalkylamine).

The SIAR covers the C12- as well as the C12-14 alkyldimethylamine (Cas-No. 84649-84-3).

Human Health

Genamin 12 R 302 D and Genamin LA 302 D have been found to be harmful following oral administration to rats. Both compounds showed strong irritating or corrosive effects after either four hours or three minutes exposure. In a 28-day subchronic toxicity study, the 'No Observed Effect Level' (NOEL) was 50 mg/kg bw/day. The reference compound Genamin 12 R 302 D was not mutagenic in the Ames test with and without metabolic activation. 302 D was also not mutagenic in a micronucleus test in vivo. The corrosive property of the compounds prompt workers to limit the potential exposure to this chemical. Due to the related self-warn effect, exposure will be self-restricted to a minimum.

Environment

N,N-dimethyldodecylamine can be classified as readily biodegradable. A high potential for adsorption onto sludge is assumed. In an activated sludge simulation test with domestic activated sludge a mean primary degradation of 99.6% was found. The following effect values were found: *Brachydanio rerio*: 96h-LC50 = 0.71 – 1 mg/l; *Daphnia magna*: 48h-EC50 = 0.083 mg/l, *Scenedesmus subspicatus*: 72h-EC50 < 23.5 µg/l and 14 µg/l. In addition ecotoxicity tests using river water as test medium are available. For the green algae *Scenedesmus subspicatus* a 72h-EC50 of 56 mg/l and a NOEC of 20 µg/l was found. In a reproduction test with Daphnia magna a 21d-NOEC of 36 µg/l was obtained. Based on these data a PNECriverwater of 0.4 µg/l can be derived using an assessment factor of 50. A sediment test with the nematode *Caenorhabditis elgans* was conducted, in which a NOEC of 1620 mg/kg dw was found. With an assessment factor of 100 a PNECsed of 16.2 mg/kg dw was derived. Acute terrestrial test with earthworm and plants are available. The lowest effect value was found for Brassica napus with an 21d-EC50 of 120 mg/kg dw for the endpoint shoot height. A PECsoil of 120 µg/kg dw can be derived from this value using an assessment factor of 1000.

Exposure

N,N-dimethyldodecylamine is produced from lauryl alcohol and dimethylamine. In 1999 C12-14 alkyldimethylamine was produced and processed in the EU in an amount of 27.000 t and in the USA in an amount of 29.500 t. There are 4 European companies and 2 US companies that produce and/or process C12-14 alkyldimethylamine. C12-14 alkyldimethylamine is used as an intermediate for manufacture of amineoxides and quarternary amino compounds.

The subsequent products are used as disinfectants; detergents; dyeing auxiliaries, wetting agents, antistatic agents and bleaching agents in textile industry; pharmacy; corrosion inhibitors; fuel oil antiicing; pourpoint additives; molecular weight regulators in plastic industry; prevention of waterspots in photography; complexing developers and dyes. Releases into the environment may occur during production, and use of the subsequent products. Processing to amineoxides and quarternary amino compounds is assumed to be a waste-water free process, therefore, no releases into the hydrosphere are expected by this life-cycle step.

NATURE OF FURTHER WORK RECOMMENDED

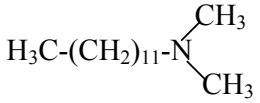
One production site was identified where risk reduction measured might be warranted.

SIDS Initial Assessment Report

1 IDENTITY

1.1 Identification of the Substance

CAS Number: 112-18-5
IUPAC Name: N,N-Dimethyldodecylamine
Molecular Formula: $C_{14}H_{31}N$
Structural Formula:



Molecular Weight: 213.41 g/mol

This SIAR covers the C12- as well as the C12-14 alkyldimethylamine (Cas-No. 84649-84-3). The latter is produced from natural precursors having a certain chain length distribution varying from source to source and is produced by far in higher tonnages than C12 amine. As the physico-chemical properties as well as the environmental behaviour and ecotoxicity of C12 and C14 alkyl dimethyl amine are rather similar, the technical mixtures are also covered by this risk assessment.

1.2 Purity/Impurities/Additives

There commercial products of the German producer Clariant (Genamin 12 R 302 D with a purity of 95 % and Genamin LA 302 D with a purity of 70 %) can be seen as examples but products from other producers can vary depending on the raw material source.

1.3 Physico-Chemical properties

Table 1 Summary of physico-chemical properties

Property	Value
Vapour pressure	1.2 Pa (20 °C)
Water solubility	10 mg/l
Partition coefficient n-octanol/water (log value)	5.47

2 GENERAL INFORMATION ON EXPOSURE

C12-14 alkyldimethylamine is produced from lauryl alcohol and dimethylamine. In Germany, there is only one production site with a volume of 8,700 t Genamin LA 302 D and 74 t Genamin 12 R 302 D. Another reference states a total volume of about 9,200 t (all figures for 1995). In 1998 the total production volume was about 11,450 t.

Recent data collected by industry state that in 1999 C12-14 alkyldimethylamine was produced and processed in the EU in an amount of 27,000 t and in the USA in an amount of 29,500 t. There are 4 European companies and 2 US companies that produce and/or process C12-14 alkyldimethylamine. The SIAR covers the releases of these 6 sites.

C12-14 alkyldimethylamine is used as an intermediate for manufacture of amineoxides, betaines and quarternary amino compounds. The subsequent products are used as (4)

- disinfectants
- detergents
- dyeing auxiliaries, wetting agents, antistatic agents and bleaching agents in textile industry
- pharmaceuticals
- corrosion inhibitors
- fuel oil antiicing
- pourpoint additives
- molecular weight regulators in plastic industry
- prevention of waterspots in photography
- complexing developers and dyes

2.1 Environmental Exposure

2.1.1 General Discussion

a) Releases into the environment

There are 5 known production sites and 6 known processing sites for C12-14 alkyldimethylamine. During production at one site no waste water occurs. At the four other production sites waste water is fed into a fat separator before being discharged into a waste-water treatment plant.

Significant releases into the atmosphere are not assumed at all 6 production/processing sites due to air srcubbing.

During processing at the 6 known sites no waste water is produced. Therefore, it is assumed that also at unknown processing sites the manufacture to amineoxides, betaines and quarternary amino compounds is also a waste-water free process.

Further releases are expected during handling and use of the subsequent products. In a commercial concentrated preparation for manufacture of consumer products, an average residue content of C12-14 alkyldimethylamine of 0.7% is reported.

The subsequent product N,N-dimethyldodecylamine oxide undergoes deoxygenation to N,N-dimethyldodecylamine at 80-100°C (4). There is no information whether the amine is formed during the use of the amine oxide.

There are no monitoring data of C12-14 alkyldimethylamine available.

b) Degradation

The biodegradability of N,N-dimethyldodecylamine was examined according to the OECD-guidelines 301 C, D and F and 302 B.

In a manometric respirometric test (OECD 301 F) employing activated sludge from a domestic sewage treatment plant as inoculum biodegradation rates of 74 % (related to theoretical COD) resp. 67 % (related to N-BOD) were found after 28 days for Genamin LA 302 D. However, the 10 day window criterion was not fulfilled.

In a closed bottle test with activated sludge from a sewage treatment plant treating predominantly domestic waste water (2 mg/l dw) a biodegradation of about 70 % after 28 days was reached. In this

test the 10 day window criterion was fulfilled (60% degradation after 10 days). The closed bottle test was also performed with river water as inoculum. (1:10 dilution of river Rhine water). In this test a total biodegradation of about 80 % after 28 days was found. After 10 days a biodegradation of 60 % was reached and therefore the 10 day window criterion is fulfilled.

In a MITI-I test (OECD 301 C) 49.4 % (on the upward trend) were degraded after 14 days.

Two Zahn-Wellens tests (OECD 302 B) were conducted using industrial activated sludge as inoculum. In one test with Genamin 12 R 302 D as test substance after 27 and 29 days an elimination of 87 % respectively of 92 % (related to DOC) was found. 3 hours after test start 46 % of the substance was adsorbed onto the sludge. Subsequently, adsorption decreased to about 33 %. Biodegradation started significantly at day 18. In the second Zahn-Wellens using Genamin LA 302 D as test substance after 8 days an elimination of the test substance of 95 % (related to COD) was achieved. 1 hour after test start 77 % of the substance was adsorbed onto the sludge. Subsequently, adsorption decreased to about 34 % after one day. The activated sludge was first collected at the surface but redispersed in the course of the test. At the end of the test the activated sludge was isolated, dried and extracted with chloroform. In the extract, long-chained amines were detectable only in traces (< 0.1 % of the charge).

From the cited test results it can be concluded that C12-14 alkyldimethylamine is readily biodegradable and a biodegradation rate constant of 1 h^{-1} is assumed for sewage treatment plants. For surface waters a half-life of 15 days can be derived from the available tests according to the TGD. A direct transfer of the result from the closed-bottle test with river water to surface waters is not possible due to the relatively high substance concentration of 2 mg/l and the test temperature of 22 °C. As microbial degradation processes are temperature dependent it is obvious that half-lives found in degradation tests that were run in the laboratory at above 20 °C cannot be transferred unrestrictedly to the environment.

A high potential for adsorption onto sludge can be derived from both Zahn-Wellens tests.

In a poorly documented study conducted by the sponsor company the elimination of C12-14 alkyldimethylamine in a laboratory sewage treatment plant was examined (5). Industrial activated sludge in a concentration of 2 g/l was used as inoculum. The hydraulic retention time of the simulation plant was about 4 h. An elimination rate of 99.99 % was found related to primary transformation of C12-14 alkyldimethylamine.

The metabolic pathway of N,N-dimethyldodecylamine was examined in several studies (6,7,8). It could be shown that metabolism of this substance generally occurs via fission of the C_{alkyl}-N bond resulting in the formation of dimethylamine and decanal. The toxicity of the parent substance is strongly reduced by this metabolisation. Therefore, in this case the primary transformation found in the simulation test can be used for the exposure calculation for the industrial wwtp from which the activated sludge was taken.

A transfer of this elimination to other industrial and to municipal sewage treatment plants is not possible due to different adaptation of activated sludge and different operational conditions in different sewage treatment plants. Therefore, a further biodegradation simulation study was performed (10). As inoculum a mixture of municipal activated sludge and inoculum from garden soil and surface water was used. The inoculum concentration for the study was 2 g/l. The hydraulic retention time of the laboratory sewage treatment plant was 6 h. An mean elimination rate of 99.6 % (range: 98.4 – > 99.99 %) was found related to primary transformation of C12-14 alkyldimethylamine. This elimination rate is used for the exposure calculation for the other industrial and for domestic sewage treatment plants.

c) Environmental distribution

N,N-dimethyldodecylamine as a tertiary amine compound is strongly basic. The pKa-value of the compound is 9.97. Therefore, it can be concluded that in the environmental relevant pH range the compound is completely protonated. The log Pow of 5.47 calculated for the amino compound is not useful for modelling the environmental distribution properties.

Experimental data about adsorption of N,N-dimethyldodecylamine onto soils or sediments are not available. In a first approach the partitioning data are derived from the data determined for the substance octadecylamine because it can be assumed that the partitioning data are in the same range:

	Kd octadecylamine	Kd used
Sludge (l/kg)	821	1000
Sediment / susp. Matter (l/kg)	6433	7000
Soil (low clay) (l/kg)	3065	3000

There are no tests on biodegradation of N,N-dimethyldodecylamine in sediments available. An accumulation of the substance is not excluded, as it has generally to be assumed (as a worst case assumption) that biodegradation only occurs in the water phase.

As N,N-dimethyldodecylamine in aqueous solutions is always protonated, no volatilisation from treatment plants or surface waters is expected.

d) Bioaccumulation

No bioaccumulation studies are available. The log Kow of 5.47 indicates a high potential for bioaccumulation. However, for surface active substances like N,N-dimethyldodecylamine the log Kow may not be suitable for calculation of a BCF value.

2.1.2 Predicted Environmental Concentration

2.1.2.1 Aquatic Compartment

Releases during production

For the 5 production sites PEC_{local} were calculated on the basis of site-specific data.

	Company A	Company B	Company C	Company D	Company E*	Company F
Data on Production			**no production**			
Measurements after fat separator						
Concentration amine (mg/l)	**14.8**			**115**		**17**
Effluent flow fat separator (m3/d)	**224**			**8**		**373**
Mass flow amine (kg/d) to wwtp	**3.315**			**0.920**		**6.341**
Waste water treatment plant						
Effluent flow wwtp (m3/d)	**100300**			**13643**		**7070**
Dilution factor sewer/wwtp	**447.8**			**1705.4**		**19.0**
Influent conc. amine (mg/l)	**0.03**			**0.07**		**0.90**
Min. removal in wwtp (%)	**99.60**			**99.6**		**99.99**
Wwtp effluent conc. (µg/l)	**1.3E-01**			**0.28**	**6,000 – 30,000**	**0.09**
Dilution						
River low flow (MNQ, m3/s)				**1050**		**2.45**
Dilution factor wwtp/river	**10**			**6650**	**10**	**30**
PEC local						
PEC local surface water (bulk) (ng/l)	**13**			**4.2E-02**	**6E+05 – 3E+06**	**3**
Fraction dissolved	**0.9**			**0.9**	**0.9**	**0.9**
PEC local surface water (dissolved) (ng/l)	**12**	**no release**		**3.8E-02**	**5.4E+05 – 2.7E+06**	**2.7**

Releases during processing

As cited above, at the 6 known processing no waste water is produced. Therefore, it can be assumed that manufacture of C12-14 alkyl dimethylamine to amineoxides, betaines and quarternary amino compounds is in general a wastewater free process and no release estimation has to be performed for this scenario.

Releases during use of subsequent products

Less information about subsequent products and their emissions are available. For the initial exposure estimation it is assumed that all subsequent products are emitted into the waste water (worst case) and that the emission is equally distributed in municipal waste water (which is a best case). For the EU consumption figures an exposure model was calculated according to the TGD. 10 % of the total consumption volume is used in 1 region. A total residue of 0.7 % C12-14 alkyl dimethylamine in subsequent products is assumed.

EU scenario:

10 % of the total EU consumption volume :		2700 t/a
0.7 % of 2700 t/a		18.9 t/a into the sewage
Consumption period:		365 d/a
Fraction of main source:		0.002
⇒ releases in domestic wwtp:		104 g/d
Sewage flow 2,000 m^3/d:	⇒	52 µg/l in the raw sewage
Elimination in wwtp 99.6%:	⇒	C_{eff} = 0.2 µg/l
Dilution 1:10	⇒	**$C_{bulk,local}$ = 20 ng/l**
90 % dissolved fraction:		**$C_{dissolved,local}$ = 18 ng/l**

As it is possible that N,N-dimethyldodecylamine is formed by deoxygenation of the subsequent product N,N-dimethyldodecylamine oxide (chapter 3.1.1) at 80-100 °C the exposure may be significantly higher.

A regional scenario was calculated with the programme EUSES for C12-14 alkyldimethylamine as impurity in follow-up products in the EU according to the TGD. A wwtp conncetion rate of 70 % is proposed in the EU scenario.

A $PEC_{regional(dissolved)}$ of 0.05 µg/l and a $PEC_{regional(bulk)}$ of 0.057 µg/l was calculated. This value is added to the calculated Clocal from use of subsequent products, as it has to be assumed that the municipal sewage treatment plant is emitting into a pre-polluted environment.

Therefore: **$PEC_{dissolved,local}$ = 18 ng/l + 50 ng/l = 68 ng/l**

$PEC_{bulk,local}$ = 20 ng/l + 57 ng/l = 77 ng/l

US Scenario

No scenario for the USA can be calculated here as no exposure model is available.

2.1.2.2 Sediment

Because of its surface-active properties, C12-14 alkyldimethylamine is expected to adsorb strongly onto sediments. The $PEC_{sediment}$ is calculated from the PEC_{aqua} using the suspended mater-water partitioning coefficient of 7000 l/kg. From this value a $K_{susp-water}$ of 1750 can be derived according to the TGD. The following PEC_{sed} can be calculated:

Production:

	$PEC_{local,aqua}$ [ng/l]	**$PEC_{local,sed}$ [µg/kg ww]**	**$PEC_{local,sed}$ [µg/kg dw]**
A	**12**	**18.3**	**47.6**
D	**3.8E-02**	**0.057**	**0.15**
E	**5.4E+05 – 2.7E+06**	**8.2E+05 – 4.1E+06**	**2.1E+06 – 1.06E+07**
F	**2.7**	**4.1**	**10.66**

Use of subsequent products:

PEC_{aqua}: 68 ng/l ⇒ **PEC_{sed} =103 µg/kg ww = 268 µg/kg dw**

2.1.2.3 Atmosphere

During production and processing no significant emissions into the atmosphere occur. In aqueous solution the substance is ionized, and volatilisation is unlikely. Overall, no significant releases into the atmosphere are expected.

2.1.2.4 Terrestrial Compartment

An exposure scenario for the terrestrial compartment was calculated assuming application of sludge from municipal waste water treatment plants. With the model Simpletreat and a Kd value for sludge of 1000 l/kg it was calculated that 23 % of the substance will adsorb to sewage sludge. A sludge concentration in a municipal sewage treatment plant of 33.7 µg/kg can be derived with this value. According to the models and input parameters proposed in the EU Technical Guidance Document (1) (10 years of sludge application, 30 days after the last application) this sludge concentration resulted in a PEClocal_soil of 120 µg/kg dw assuming a half-life in soil of 500 days (This half-life is derived for the substance dimethyloctadecylammonium chloride (DODMAC). With a Kd of 10,000 l/kg adsorption is similar to those of the C12-14 alkyldimethylamine, thus the influence of adsorption onto biodegradation is expected to be similar. DODMAC was classified as inherently degradable, based on several laboratory tests the half-life for soils was determined to 500 days (EU 2002). C12-14 alkyl amine is readily biodegradable, thus a lower half-life than 500 days is expected). The local soil porewater concentration is 0.04 µg/l.

3 HUMAN HEALTH HAZARDS

3.1 Effects on Human Health

3.1.1 Acute Toxicity

Studies in Animals

The acute oral toxicity of Genamin 12 R 302 D is considered to be moderate. LD50 values after single oral administration are 1890 mg/kg bw for male rats and 1450 mg/kg bw for female rats.

Single oral administration of Genamin LA 302 D by gavage to female rats revealed a LD50 of 1200 mg/kg bw. All tests mentioned were carried out according to OECD-guideline 401.

The data on skin irritation with rabbits indicate strong irritation by the tested Genamin LA 302 D and Genamin 12 R 302 D. Both compounds tested according OECD-guideline 404 showed corrosive effects after either four hours or three minutes exposure.

Studies in Humans

No data are available.

Conclusion

	harmful if swallowed
	causes severe burns
Recommendation:	no need for follow-up test
Priority setting:	low priority or concern

3.1.2 Repeated Dose Toxicity

Studies in Animals

In a 28-day subchronic toxicity study according to OECD-guideline 407, dodecyldimethylamine was administered by gavage daily to four groups each consisting of 5 Sprague-Dawley-Rats in test concentrations of 0 (control), 50, 150 or 300 mg/kg bw. Toxicological examinations were carried out on mortalities, clinical signs, body weight, food consumption, examination of eyes, haematology, clinical biochemistry, urinalysis, organ weights, macroscopic post mortem findings and histopathology.

The highest dose group (300 mg/kg bw/day) was within the lethal range. Three of the five females died between test day 5 and 28. None of the male animals died. No substance-related changes were found at histopathology in the surviving animals. No mortalities occurred in the 50 and 150 mg/kg group. No substance-related influence on behaviour and external appearance was evident in the 50 mg/kg group. In the 150 mg/kg group all animals showed rubbing of the snouts in the bedding material between test days 2 and 28 immediately after dosing for a duration of approximately 5 minutes.

Body weight, food consumption, haematology, clinical biochemistry, urinalysis and organ weights showed no substance-related influence in animals after dosing of 50 or 150 mg/kg bw/day.

Based on these findings the ‘No Observed Effect Level’ (NOEL) was 50 mg dodecyldimethylamin/kg bw/day by gavage for 28 days.

Studies in Humans

There are no data available.

Conclusion

No specific target organs detected. Only unspecific signs of toxicity observed. NOEL = 50 mg/kg bw/day.

Recommendation: No need for follow-up test

Priority setting: Low priority or concern

3.1.3 Mutagenicity

Studies in Animals

In vitro Studies

Genamin 12 R 302 D was tested for mutagenicity with the strains TA 100, TA 1535, TA 1537, TA 1538, TA 98 of Salmonella typhimurium (Ames test) and Escherichia coli WP2uvrA.

The mutagenicity studies were conducted in the absence and in the presence of a metabolizing system derived from rat liver homogenate. A dose range from 0.16 microgram/plate to 500 microgram/plate was used. Genamin 12 R 302 D did not show in these bacterial test systems either with or without exogenous metabolic activation at the dose levels investigated a dose dependent increase in the number of revertants in any of the bacterial strains. Based on this results it can be stated that Genamin 12 R 302 D is not mutagenic in these bacterial test systems.

In vivo Studies

Genamin LA 302 D was tested also for chromosomal mutations in a micronucleus test in vivo. Male and female mice were given the test compound in sesam oil twice at an interval of 24 hours as orally doses of 120, 400 and 1200 mg per kg body weight. As a result, the number of polychromatic erythrocytes containing micronuclei was not increased. The ratio of polychromatic erythrocytes to total erythrocytes in both male and female animals remained also unaffected. Based on the results it can be stated that Genamin LA 302 D is not mutagenic in the micronucleus test.

Studies in Humans

No data are available.

Conclusion

Based on the available data dodecyldimethylamine does neither cause point mutation effects nor chromosomal mutations. No further assessment of dodecyldimethylamine is necessary with regard to genetic toxicity.

3.1.4 Carcinogenicity

No data available.

3.1.5 Toxicity for Reproduction

Studies in Animals

A reproduction/development toxicity screening test of dodecyldimethylamine by oral administration to Sprague-Dawley-Rats according OECD method 421 was carried out with five groups of 10 male and 10 female rats each. The rats received 0 (control), 50, 150, 300 or 450 mg/kg bw/day; males: 14 days prior to mating and during the 14-day mating period , females: 14 days prior to mating and during the mating period, pregnancy and lactation period.

Examinations were carried out on mortality, clinical signs, body weight, food consumption, reproduction, macroscopic post-mortem findings/organ weights of parent animals and histopathology.

The 450 mg/kg test group was discontinued on the 5th day of test because 1 male and 2 females died during the night of test day four and the remaining rats showed a poor general condition.

300 mg/kg led to premature death of the male no. 87 on the 5th day of the mating period. Six females of this group died between the 10th pregnancy and 3rd lactation day. Only one female pup alive was born in this group.

At 150 mg/kg the female animals no. 53 and 59 died during the night of the 22nd pregnancy day and on the 3rd lactation day respectively. The parturition of 2 dams (no. 57 and 58) was influenced; they did not deliver any pups at all. This dose level lies within the toxic range for pups. The number of pups alive on the day of delivery was significantly decreased, the number of stillbirths significantly increased. The birth weight of the male pups was decreased, the weight of female pups was within the normal range.

The mean post-implantation loss was significantly increased to 50.4 % (control: 13.3 %).

The mean viability index was significantly decreased to 36.9 % (control: 99.3 %).

The brood care of several dams was influenced: the umbilical cord remained unsevered, pups were cannibalized, the pups were found scattered in the bedding material.

150 mg/kg were in the beginning lethal range for pregnant rats and in the toxic range for embryos/fetuses/pups.

None of the male and female animals at the 50 mg/kg group showed any changes of behavioural and external appearance. In this group there were no substance-related differences in body weight and body weight gain during all phases of the study, all values found for relative food consumption were within the normal range. 50 mg/kg did not influence the reproduction parameter of rats. Mean pre-coital time and duration of pregnancy were within the normal range. The parturition was inconspicuous. The post-implantation loss (approx. 13 %) and viability index (approx. 99%) were similar to those of the control. The number of pups born was not affected, the pups developed normally. Body weight and sex ratio of the pups were not influenced.

In the reproduction/developmental toxicity screening test with rats the ‘No Observed Effect Level’ (NOEL) for both parent animals and their pups was 50 mg dodecyldimethylamine/kg bw/day by gavage.

Studies in Humans

There are no data available.

Conclusion

In the above mentioned studies, a clear-cut 'No Observed Effect Level' (NOEL) of 50 mg dodecyldimethylamine kg bw/day, by gavage, was determined for both parent animals and their pups. The same NOEL of 50 mg/kg bw/day, by gavage, was determined in this species after a 28-day treatment period. Toxicity for parent animals, toxicity and/or lethality for embryos/fetuses/pups as well as influence on the fertility is observed only at higher dose levels.

Recommendations:

Based on the results of the 28-day toxicity test and the reproduction/developmental toxicity screening test, no further assessment of dodecyldimehtylamine on reproductive toxicity is necessary.

Priority setting: low priority or concern

3.2 Initial Assessment for Human Health

The reference compound Genamin 12 R 302 D (> 95 % C12-Dimethyldodecylamine) and the structural related Genamin LA 302 D (approximately 70 % C12-, 25 % C12-14- and 5 % C16-dimethylalkylamine) have been found to be harmful following oral administration to rats. Both compounds showed strong irritating or corrosive effects after either four hours or three minutes exposure. In a 28-day subchronic toxicity study, the 'No Observed Effect Level' (NOEL) was 50 mg/kg bw/day. The reference compound Genamin 12 R 302 D was not mutagenic in the Ames test with and without metabolic activation. 302 D was also not mutagenic in a micronucleus test in vivo. The corrosive property of the compounds prompt workers to limit the potential exposure to this chemical. Due to the related self-warn effect, exposure will be self-restricted to a minimum.

4 HAZARDS TO THE ENVIRONMENT

4.1 Aquatic Effects

The following results from ecotoxicity tests are available:

Brachydanio rerio	96 h-LC_0 = 0.5 mg/l
(static, nominal concentration, test substance:Genamin 12 R 302 D,	96 h-LC_{50} = 0.71 - 1 mg/l
ethanol as solubilizer)	96 h-LC_{100} = 1 mg/l
Daphnia magna:	48 h-LC_0 < 0.06 mg/l
(effect: immobilization, test substance: Genamin LA 302 D,	48 h-LC_{50} = 0.083 mg/l
Tween 80 as solubilizer,)	48 h-LC_{100} = 0.16 mg/l

Analytical monitoring of the test concentration showed that the concentrations decreased within 48 h to an average of 57.4 % of the nominal concentration. All effect values were therefore calculated to 57.4 % of the respective nominal concentration. The concentration decreases may be due to adsorption.

Scenedesmus subspicatus:	72 h-E_bC_{10} ≤ 4.7 µg/l
(effect: growth inhibition related to biomass resp. growth rate, test	72 h-E_rC_{10} ≤7 µg/l
substance: Genamin LA 302 D, Tween 80 as solubilizer,)	72 h-E_bC_{50} ≤13.3 µg/l
	72 h-E_rC_{50} ≤ 23.5 µg/l

After 72 h no analytical monitoring of the test substance was possible as the concentrations were below the detection limit. Immediately after the start of the test analytical monitoring was conducted in the highest tested concentration (50 µg/l). 80 % of the nominal concentration was found. Therefore all reported concentrations were calculated to 80 % of the respecitve nominal concentration. As in the test with *Daphnia magna* an average decrease to 57.4 % of the nominal concentration was observed it is to be expected that in the algae test similar concentration decreases occur. Therefore, all effective concentrations were reported with "≤".

A further algae growth inhibition test with *Scenedesmus subspicatus* was recently conducted (11). Two different natural waters from the rivers "Elbe" and "Boehme" were used. In addition a parallel test with OECD medium was performed, however, only with two test concentrations. The following effect values, all related to nominal concentrations, were found:

River Elbe water (industrial characterized region):

72h-E_bC50 = 56 µg/l

72h-NOEC (biomass) = 20 mg/l

72h-E_rC50 = 92 µg/l

72h-NOEC (growth rate) = 20 µg/l

River Boehme water (agricultural characterized region):

72h-E_bC50 = 34 µg/l

72h-NOEC (biomass) = 10 µg/l

72h-E_rC50 = 56 µg/l

72h-NOEC (growth rate) = 20 µg/l

OECD test medium:

72h-E_bC50 = 6 µg/l

72h-E_rC50 = 14 µg/l

NOEC < 10 µg/l (for biomass and growth rate)

With the water from river "Boehme" as test medium also a long-term test with *Daphnia magna* according to OECD GL 211 was performed (13). The test method was semi-static with a renewal of test medium three times per week. The concentration of suspended matter in the river water was approximatley 19 mg/l representing typical conditions of German rivers. A NOEC for reproduction of 36 µg/l and a LOEC of 0.108 µg/l were found related to nominal concentrations. Analytical monitoring of the test substance concentration showed that after 2 days no test substance could be detected in the aqueous phase with a detection limit of 150 µg/l. As both adsorption onto the glass walls of test beakers as well as biodegradation can be excluded it is assumed that the C12-14 alkyldimethylamine was adsorbed onto suspended particles.

Tests with microorganisms:

activated sludge, domestic	3 h-EC_{20} = 5.6 mg/l
(nominal concentration, effect: respiration inhibition,	3 h-EC_{50} = 27.3 mg/l
test substance: Genamin 12 R 302 D)	3 h-EC_{80} > 1000 mg/l
acitvated sludge, domestic	3 h-EC_{10} = 50 mg/l
(nominal concentration, effect: respiration inhibition,	3 h-EC_{50} = 80 mg/l
test substance: Genamin LA 302 D)	3 h-EC_{80} = 110 mg/l

Derivation of $PNEC_{aqua}$

The most sensitive species to N,N-dimethyldodecylamine was the green algae *Scenedesmus subspicatus*. Several tests with OECD medium and river water are available for this species.

It is assumed that tests with river water are more relevant for surface active substances like C12-14 aklyldimethylamine, because adsorption losses and complexation with dissolved colloidal anionic substances can be better reflected than in a test with laboratory water. Therefore, a $PNEC_{riverwater}$ is derived from the available studies that has to be compared with the PEC_{bulk}. Long-term tests with algae and daphnids performed with river water are available. The lowest NOEC was 20 µg/l found for the green alga *Scenedesmus suspicatus*. Using an assessment factor of 50 gives:

PNECaqua_riverwater = 20 µg/l / 50 = 0.4 µg/l

Sediments

The effects of C12-14 alkyldimethylamine on the nematode *Caenorhabditis elgans* were studied (9). Test parameters were growth, egg production and fertility. First stage juveniles of the test species were exposed for 72 h to a mixture of spiked artificial sediment (organic carbon content: 2 %) and a suspension of E. coli. The bacteria served as food for the nematodes. So, the test organisms are exposed to the chemical via sediment, porewater and food. After 72 h a NOEC of 1620 mg/kg dw related to nominal concentration was found. At the next concentration, 2030 mg/kg dw 100 % inhibition of fertility and egg production was observed. Growth was also significantly inhibited at this concentration.

From the NOEC of 1620 mg/kg dw a PNECsed can be derived by applying an assessment factor of 100. This factor is chosen because one long-term test with benthic species is available.

Therefore: **PNECsed = 1620 mg/kg dw / 100 = 16.2 mg/kg dw**

However, it has to be kept in mind that the real effect concentrations could be lower due to possible degradation of the test substance during the test.

4.2 Terrestrial Effects

The acute toxicity of C12-14 alkyldimethylamine (Genamine LA 302 D) to the earthworm *Eisenia fetida* was determined in a limit test acording to OECD GL 207 with artificial soil (12). At the only tested concentration of 1000 mg/kg dw no effects on mortality, behaviour and body weight were found.

For 3 different plant species (*Avena sativa*, *Brassica napus* and *Trifolium pratense*) acute toxicity tests with C12-14 alkyldimethylamine (Genamine LA 302 D) were performed (14). A seed emergence test over 21 days was conducted. The determined endpoints were shoot height, fresh weight and number of emerged seedlings. The following effect values were obtained:

Avena sativa:	21d-EC50 > 1000 mg/kg dw (shoot height)
	21d-EC50 = 700 mg/kg dw (fresh weight)
	21d-EC50 > 1000 mg/kg dw (seed emergence)
Brassica napus:	21d-EC50 = 120 mg/kg dw (shoot height)
	21d-EC50 = 127 mg/kg dw (fresh weight)
	21d-EC50 = 586 mg/kg dw (seed emergence)

Trifolium pratense: 21d-EC50 = 159 mg/kg dw (shoot height)
21d-EC50 = 188 mg/kg dw (fresh weight)
21d-EC50 = 237 mg/kg dw (seed emergence)

The inhibitory effect of N,N-dimethyldodecylamine on brood development of the wood-boring beetle *Xyleborus fornicatus* was examined. Effects were evaluated on the basis of the number of emerging young adult females. 50 ppm (the lowest concentration tested) incorporated into the diet were found to be strongly suppressive to beetle brood development.

Only from the tests with earthworms and plants a PNECsoil can be derived as in the test with *Xyleborus fornicatus* the test substance was applied via the diet. The lowest effect values was found for *Brassica napus* (21d-EC50 = 120 mg/kg dw) for the endpoint shoot height. As only short-term tests with terrestrial organisms are available, an assessment factor of 1000 is applied to this value.

Therefore: **PNECsoil = 120 mg/kg dw / 1000 = 120 µg/kg dw**

4.3 Initial Assessment for the Environment

Aquatic compartment

With a $PNEC_{riverwater}$ of 400 ng/l and a $PNEC_{sed}$ of 16.2 mg/kg dw, the exposure/effect ratios are:

	PEC_{aqua}, bulk [ng/l)	**PEC/ $PNEC_{riverw.}$**	**PEC_{sed} [µg/kg dw]**	**PEC/ $PNEC_{sed}$**
Production				
A	13	0.03	47.6	2.9E-03
B	0	-	0	-
C	0	-	0	-
D	4.2E-02	1E-04	0.015	9.6E-07
E	5.4E+05 – 2.7E+06	1350 - 6750	2.1E+06 - 1.06E+07	130 - 654
F	3	7.5E-03	10.7	6.6E-04
Use of follow-up products	77	0.19	268	1.6E-02

The PEC/PNEC ratios for the aquatic compartment for the production site E is > 1. The PEC/PNEC ratio for the sediment compartment for the production site E is > 1. Therefore, a risk to the aquatic environment and the sediment compartment has to be expected.

Terrestrial compartment

A comparison of the PECsoil of 120 µg/kg dw with the PNECsoil of 120 µg/kg dw results in a PEC/PNEC ratio of 1. Thus, a risk to the terrestrial compartment due to use of subsequent products is not to be expected. For the interpretation of this result it has to be considered that the PECsoil is based on worst-case assumptions. Thus, a PEC/PNEC ration < 1 is rather to be expected.

5 CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

The initial environmental risk assessment resulted in PEC/PNEC ratios >1 for the production site E. Thus, a risk to aquatic compartment (incl. sediment) has to be expected. As the calculation of the

PEC is already based on measured effluent concentrations, an improvement of the data basis is not possible.

Based on the values for human toxicity, there is no need for further studies nor for suggestions for other measures in this field.

5.2 Recommendations

One production site was identified where risk reduction measured might be warranted.

6 REFERENCES

1. Technical Guidance Documents in Support of the Commission Directive 93/67/EEC on the Risk Assessment for New Notified Substances and the Commission Regulation (EC) 1488/94 on Risk Assessment for Existing Substances

2. Veith G.D. et al. 1979: Measuring and Estimating the Bioconcentration Factor of Chemicals in Fish; J. Fish Board Can. 36, 1040-1048

3. BUA Report 177: Primary Fatty Amines. Ed. by the GDCh Advisory Committee on Existing Chemicals of Environmental Relevance.

4. „Amine Oxides"; in: Kirk-Othmer Enzyclopedia of Chemical Technology, 4th Edition

5. InfraServ 1999: Abbauversuch mittels Laborkläranlage, unpublished report

6. van Ginkel et al. 1995: Biodegradation of fatty amines, Tenside Surf. Det. 32,4, 355-359

7. van Ginkel 1996: Complete degradation of xenobiotic surfactants by consortia of aerobic microorganisms, Biodegradation 7, 151-164

8. Kroon et al 1994: Metabolism of dodecyldimethylamine by Pseudomonas MA3, Applied Microbiol Biotechnol. 42, 134-139

9. BSB 2000: Toxicity of sodium tetrapropenyl benzene sulfonate, cocos dimethylamine, di hardened tallow dimethyl ammonium chloride and tallow alkylamine on the nematode Caenorhabditis elegans in artificial sediment.

10. InfraServ 2000: Genamin LA 302 D: Simulation Test – Aerobic Sewage Treatment: Coupled Units Test.

11. Noack (2000a): Genamin LA 302 D: Alga growth inhibition test with two natural river waters with Scenedesmus subspicatus, 72 h. Project No. 000907CK, Study No. SSO7535N

12. Noack (2000b): Genamin LA 302 D: Earthworm (Eisenia fetida), Acute toxicity test in artificial soil, Limit test. Project No. 000907CK, Study No. RRA 75351

13. Noack (2001): Genamin LA 302 D: Daphnia magna reproduction test (21 d) with natural river water. Project No. 001114CK, Study No. DRE75351

14. Noack (2001): Genamin LA 302 D: Terrestrial plants toxicity, seedling emergence. Project No. 000907CK, Study No. TNC75353

I U C L I D

D a t a S e t

Existing Chemical ID: 84649-84-3
CAS No. 84649-84-3
EINECS Name Amines, C12-14-alkyldimethyl
EC No. 283-464-9
Molecular Weight 227
Molecular Formula C14-H31-N,C16-H35-N blend

Producer Related Part
Company: Clariant GmbH
Creation date: 14-OCT-2002

Substance Related Part
Company: Clariant GmbH
Creation date: 14-OCT-2002

Memo: IUCLID/SAP EH&S Import V4.0

Printing date: 17-AUG-2004
Revision date: 14-OCT-2002
Date of last Update: **17-AUG-2004**

Number of Pages: **50**

Chapter (profile): Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile): Reliability: without reliability, 1, 2, 3, 4
Flags (profile): Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 Applicant and Company Information

Type: cooperating company
Name: Albemarle S.A.
Contact Person: Dr. J. Vermeulen **Date:** 02-JUN-1995
Street: Aveenue Louise 523, Bte 19
Town: B-1050 Bruxelles
Country: Belgium

16-DEC-2002

Type: cooperating company
Name: FINA Research
Country: Belgium

16-DEC-2002

Type: cooperating company
Name: Akzo Nobel
Country: Sweden

16-DEC-2002

1.0.2 Location of Production Site, Importer or Formulator

1.0.3 Identity of Recipients

1.0.4 Details on Category/Template

1.1.0 Substance Identification

1.1.1 General Substance Information

Substance type: organic
Physical status: liquid
Purity: >= 95 - % w/w

Remark: (C12-C14)-Alkyldimethyamine is a mixture containing ca. 70 % C12 - and ca. 30 % C14-alkyldimethylamine Chapter 2 - 5 are also submited in the name of: Akzo Nobel Surface Chemistry AB, Schweden Albemarle S.A., Belgien Fina Research, Belgien
04-AUG-2004 (1)

1.1.2 Spectra

1.2 Synonyms and Tradenames

(Dimethylamino)dodecane (112-18-5)

16-DEC-2002

1-Dodecanamine, N,N-dimethyl- (112-18-5)

16-DEC-2002

Amines, C12-14-alkyldimethyl

16-DEC-2002

C12-14-alkyldimethylamines

16-DEC-2002

Dimethyllaurylamin

16-DEC-2002

Dodecylamine, N,N-dimethyl- (112-18-5)

16-DEC-2002

Genamin 12 R 302 D (Trade name)

16-DEC-2002

Genamin LA 302 D (Trade name)

16-DEC-2002

Lauryldimethylamine (112-18-5)

16-DEC-2002

N,N-Dimethyl-n-dodecylamine (112-18-5)

16-DEC-2002

N,N-Dimethyldodecylamine (112-18-5)

16-DEC-2002

N,N-Dimethyllaurylamine (112-18-5)

16-DEC-2002

N-Dodecyl-N,N-dimethylamine (112-18-5)

16-DEC-2002

N-Dodecyldimethylamine (112-18-5)

16-DEC-2002

N-Lauryldimethylamine (112-18-5)

16-DEC-2002

1.3 Impurities

1.4 Additives

1.5 Total Quantity

Quantity: 10000 - 50000 tonnes produced in 1992

Remark: Estimated production in Germany
19-DEC-2002 (2)

Quantity: 10000 - 50000 tonnes produced in 1996

19-DEC-2002 (3)

Quantity: 10000 - 50000 tonnes produced in 1997

19-DEC-2002 (4)

1.6.1 Labelling

Labelling: provisionally by manufacturer/importer
Symbols: (N) dangerous for the environment
(C) corrosive
R-Phrases: (22) Harmful if swallowed
(34) Causes burns
(50) Very toxic to aquatic organisms
S-Phrases: (26) In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
(28) After contact with skin, wash immediately with plenty of ...
(36/37/39) Wear suitable protective clothing, gloves and eye/face protection
(45) In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
(61) Avoid release to the environment. Refer to special instructions/Safety data sets

Remark: Kennzeichnung nach CESIO (1995)
19-DEC-2002 (5)

1.6.2 Classification

Classified: provisionally by manufacturer/importer
Class of danger: harmful
R-Phrases: (22) Harmful if swallowed

16-DEC-2002 (5)

Classified: provisionally by manufacturer/importer
Class of danger: corrosive
R-Phrases: (34) Causes burns

16-DEC-2002 (5)

Classified: provisionally by manufacturer/importer
Class of danger: dangerous for the environment

R-Phrases: (50) Very toxic to aquatic organisms

16-DEC-2002 (5)

1.6.3 Packaging

1.7 Use Pattern

Type: industrial
Category: Chemical industry: used in synthesis

Source: Hoechst AG Frankfurt/Main
16-DEC-2002

Type: type
Category: Non dispersive use

Source: Hoechst AG Frankfurt/Main
16-DEC-2002

Type: use
Category: Intermediates

Country: Germany
Remark: Intermediate for manufacture of amineoxides and quaternary compounds.
Source: Hoechst AG Frankfurt/Main
Test substance: (C12-C14)-Alkyldimethylamine
16-DEC-2002 (6)

Type: use
Category: Intermediates

Remark: Intermediate for manufacture of disinfectants.
Test substance: (C12-C14)-Alkyldimethylamine
16-DEC-2002 (6)

1.7.1 Detailed Use Pattern

1.7.2 Methods of Manufacture

1.8 Regulatory Measures

1.8.1 Occupational Exposure Limit Values

1.8.2 Acceptable Residues Levels

1.8.3 Water Pollution

Classified by: other
Class of danger: 2 (water polluting)

Country: Germany

Remark: Base of water hazard class: Water Hazard Class (Germany)
Classification by producer
Test substance: Genamin LA 302 D
16-DEC-2002 (5) (7)

1.8.4 Major Accident Hazards

Legislation: Stoerfallverordnung (DE)
Substance listed: no

Country: Germany
16-DEC-2002

1.8.5 Air Pollution

Classified by: other
Number: 3.1.7 (organic substances)
Class of danger: III

Country: Germany
Remark: 3.1.7 organic substances: Class III
Base of Classification: Hoechst AG (Provisional)
Test substance: Genamin LA 302 D
19-DEC-2002 (8)

1.8.6 Listings e.g. Chemical Inventories

1.9.1 Degradation/Transformation Products

1.9.2 Components

1.10 Source of Exposure

Remark: Release of (C12-C14)-dimethylamine: 1. Release during production at Clariant site Release to waste water before wwtp: 0.01 % based on produced tonnage No release to air and soil 2. Release during use at Clariant sites No release to air, waste water and soil 3. Release of (C12-C14)-alkyldimethylamines as impurity in follow up products (Quats, Betaines, Amine oxides) Follow up Clariant products contain ca. 0.7 % starting material (C12-C14)-alkyldimethylamines which will be released to waste water during use of the follow up products. No release to air. Release to soil via sludge application to soil possible.
04-AUG-2004 (9)

1.11 Additional Remarks

1.12 Last Literature Search

1.13 Reviews

2.1 Melting Point

Value: -20 degree C
Sublimation: no

Method: other

Method: no data
Remark: solid/liquid
Type: Melting Point
Test condition: no data
Test substance: N,N-Dodecyldimethylamine; no information about purity
Reliability: (4) not assignable
04-AUG-2004 (10)

Value: < -10 degree C
Sublimation: no

Method: other

Method: DIN/ISO 3016
Remark: Pourpoint
solid/liquid
Type: Melting Point
Reliability: (4) not assignable
04-AUG-2004 (5)

Value: < -15 degree C
Sublimation: no

Method: other

Method: DIN/ISO 3016
Remark: solid/liquid
Type: Melting Point
Test substance: Genamin LA 302 D
Reliability: (4) not assignable
04-AUG-2004 (1)

2.2 Boiling Point

Value: 271 degree C at 1013 hPa

Remark: liquid/gaseous
Type: Boiling Point
Test substance: N,N-Dodecyldimethylamin
Reliability: (4) not assignable
04-AUG-2004 (11)

2.3 Density

Type: density
Value: .7846 g/cm³ at 25 degree C

Method: other

Method: no data
Test condition: no data

Test substance: N,N-Dodecyldimethylamine; no information about purity
Reliability: (4) not assignable
04-AUG-2004 (10)

Type: density
Value: .76 g/cm³ at 60 degree C

Method: other

Method: DIN 51757
Source: Hoechst AG Frankfurt/Main
Reliability: (4) not assignable
04-AUG-2004 (12)

Type: density
Value: .77 g/cm³ at 60 degree C

Method: other

Method: DIN 51757
Test substance: Genamin 12 R 302 D
Reliability: (4) not assignable
04-AUG-2004 (1)

2.3.1 Granulometry

2.4 Vapour Pressure

Value: 13.33 hPa at 135 degree C

Reliability: (2) valid with restrictions
04-AUG-2004 (13)

Value: 1.33 hPa at 90 degree C

Test condition: No data
Test substance: N,N-Dodecyldimethylamine; no information about purity
Reliability: (2) valid with restrictions
04-AUG-2004 (14)

Remark: No experimental data at 20 degree C available. Extrapolation of vapour pressures from data at higher temperatures (90 - 271 degree C): 0.012 hPa at 20 degree C 0.018 hPa at 25 degree C
Reliability: (2) valid with restrictions
04-AUG-2004 (15)

2.5 Partition Coefficient

log Pow: 5.47

Method: other (calculated)

Method: Mechem Software CLOGP3, Release 3.42, Pomona College, Clermont CA
Test substance: N,N-Dodecyldimethylamin (C12)
Reliability: (2) valid with restrictions

04-AUG-2004 (16)

log Pow: 5.44

Method: other (calculated)

Method: SRC LOGKOW v1.51
Test substance: N,N-Dodecyldimethylamin (C12)
Reliability: (2) valid with restrictions
04-AUG-2004 (17)

log Pow: 6.42

Method: other (calculated)

Method: SRC LOGKOW v1.51
Test substance: N,N-Tetradecyldimethylamin (C14)
Reliability: (2) valid with restrictions
04-AUG-2004 (17)

2.6.1 Solubility in different media

Solubility in: Water
Value: 8.6 mg/l at 25 degree C

Method: other

Method: calculated SRC WSKOW v1.33
Test substance: N,N-Dodecyldimethylamin (C12)
Reliability: (2) valid with restrictions
04-AUG-2004 (18)

Solubility in: Water
Value: .9 mg/l at 25 degree C

Method: other

Method: calculated SRC WSKOW v 1.33
Test substance: N,N-Tetradecyldimethylamin (C14)
Reliability: (2) valid with restrictions
04-AUG-2004 (18)

Solubility in: Water
Descr.: not soluble
Test substance: (C12-C14)-Alkyldimethylamine
Reliability: (4) not assignable
04-AUG-2004 (12)

pKa: 9.97 at 25 degree C

Method: other

Method: calculated pKalc 3.2
Remark: Due to the high pKa N,N-Dodecyldimethyamin (C12) is almost fully protonated in aquatic environments
Test substance: N,N-Dodecyldimethylamin (C12)
Reliability: (2) valid with restrictions
04-AUG-2004 (19)

Solubility in: Water

Value: ca. 10 mg/l at 30 degree C

Method: Directive 84/449/EEC, A.6
GLP: yes

Reliability: (1) valid without restriction
Guideline Study
16-DEC-2002 (20)

2.6.2 Surface Tension

2.7 Flash Point

Value: > 100 degree C

Method: other
GLP: no data

Method: DIN / ISO 2592
Reliability: (4) not assignable
04-AUG-2004 (5) (1)

Value: > 122 degree C
Type: closed cup

Method: other

Method: Pensky-Martens
Reliability: (2) valid with restrictions
04-AUG-2004 (21)

2.8 Auto Flammability

2.9 Flammability

2.10 Explosive Properties

2.11 Oxidizing Properties

2.12 Dissociation Constant

2.13 Viscosity

2.14 Additional Remarks

3.1.1 Photodegradation

Type: air
INDIRECT PHOTOLYSIS
Sensitizer: OH
Conc. of sens.: 500000 molecule/cm³
Rate constant: .00000000012 cm³/(molecule * sec)
Degradation: ca. 50 % after .2 day(s)

Method: other (calculated)
Test substance: other TS

Method: according to Atkinson
Test substance: N,N-Dodecyldimethylamin
Reliability: (2) valid with restrictions
04-AUG-2004 (8)

3.1.2 Stability in Water

3.1.3 Stability in Soil

3.2.1 Monitoring Data (Environment)

3.2.2 Field Studies

3.3.1 Transport between Environmental Compartments

3.3.2 Distribution

3.4 Mode of Degradation in Actual Use

3.5 Biodegradation

Type: aerobic
Inoculum: activated sludge, industrial
Concentration: 200 mg/l related to DOC (Dissolved Organic Carbon)
Degradation: 92 % after 29 day(s)
Result: inherently biodegradable
Kinetic:

3 hour(s)	46 %
4 day(s)	34 %
11 day(s)	33 %
15 day(s)	40 %
27 day(s)	87 %

Method: OECD Guide-line 302 B "Inherent biodegradability: Modified Zahn-Wellens Test"
GLP: no data
Test substance: other TS

Test condition: Concentration of inoculum: wet ca. 12 g/l, dry ca. 1 g/l
Test substance: N,N-Dodecyldimethylamin
Reliability: (2) valid with restrictions
04-AUG-2004 (22)

Type: aerobic
Inoculum: activated sludge, industrial

Concentration: 250 mg/l related to Test substance
Degradation: 95 % after 8 day(s)
Kinetic:
1 hour(s)	77 %
1 day(s)	34 %
4 day(s)	89 %
6 day(s)	92 %

Method: OECD Guide-line 302 B "Inherent biodegradability: Modified Zahn-Wellens Test"
GLP: no
Test substance: other TS

Remark: About 80 % of the COD have been eliminated (through adsorption) immediately after beginning of testing. The activated sludge was collected at the surface. In the continuing process the test substance has been resuspended and eliminated quickly and completely. The activated sludge was isolated, dried and extracted with chloroform after finishing test. In the extract long-chained amines were detectable only in traces (<0.1 % of the charge) within the extract. Detection with GC/spectral photometry.
No information about origin and concentration of sludge.
Reliability: (4) not assignable
04-AUG-2004 (23)

Type: aerobic
Inoculum: activated sludge, domestic
Concentration: 13 mg/l related to Test substance
Degradation: 67 % after 28 day(s)
Kinetic:
7 day(s)	44 %
14 day(s)	48 %
21 day(s)	59 %

Method: OECD Guide-line 301 F "Ready Biodegradability: Manometric Respirometry Test"
GLP: yes
Test substance: as prescribed by 1.1 - 1.4

Remark: The substance was added directly to diluent water; degradation rate related to N-BOD.
Result: 10d-widnow not fulfilled.
Reliability: (2) valid with restrictions
04-AUG-2004 (24)

Type: aerobic
Inoculum: activated sludge, non-adapted
Concentration: 100 mg/l related to Test substance
Degradation: 49.4 % after 14 day(s)

Method: OECD Guide-line 301 C "Ready Biodegradability: Modified MITI Test (I)"
GLP: no data
Test substance: other TS

Test substance: Lauryldimethylamine
Reliability: (2) valid with restrictions
04-AUG-2004 (25)

Type: aerobic
Inoculum: predominantly domestic sewage, non-adapted
Concentration: 13 mg/l related to Test substance

Degradation: 74 % after 28 day(s)
Kinetic: 7 day(s) 48 %
14 day(s) 53 %
21 day(s) 64 %

Method: OECD Guide-line 301 F "Ready Biodegradability: Manometric Respirometry Test"
GLP: no
Test substance: other TS

Remark: The substance was added directly to diluent water; degradation rate related to thCOD.
Result: 10d-window not fulfilled.
Test substance: (C12-C14)-Alkyldimethylamine
Reliability: (2) valid with restrictions
04-AUG-2004 (24)

Type: aerobic
Inoculum: activated sludge, domestic
Concentration: 2 mg/l related to Test substance
Degradation: 67 % after 28 day(s)
Result: readily biodegradable
Kinetic: 5 day(s) 52 %
15 day(s) 63 %
28 day(s) 67 %

Method: OECD Guide-line 301 D "Ready Biodegradability: Closed Bottle Test"
GLP: yes
Test substance: other TS

Test substance: Dodecyldimethylamine, distilled; purity: ca. 100 %
Reliability: (2) valid with restrictions
04-AUG-2004 (26)

Type: aerobic
Inoculum: activated sludge, domestic
Concentration: 2 mg/l related to Test substance
Degradation: 81 % after 28 day(s)
Result: readily biodegradable
Kinetic: 5 day(s) 45 %
15 day(s) 61 %

Method: OECD Guide-line 301 D "Ready Biodegradability: Closed Bottle Test"
GLP: yes
Test substance: other TS

Test substance: Alkyl(C12-14)dimethylamine; purity: ca. 100 %
04-AUG-2004 (27)

Type: aerobic
Inoculum: activated sludge, domestic
Concentration: 100 mg/l related to Test substance
Degradation: 55 % after 15 day(s)

Method: other
GLP: no data
Test substance: other TS

Method: CO2 production measurement

Test condition: 25 degree C, inoculum 30 mg/l
Test substance: Genamin 12 R 302 D
Reliability: (2) valid with restrictions
04-AUG-2004 (28)

Type: aerobic
Inoculum: activated sludge, domestic
Concentration: 100 mg/l related to Test substance
Degradation: 66 % after 15 day(s)

Method: other
GLP: no data
Test substance: other TS

Method: oxygen consumption measurment
Test condition: 25 degree C, inoculum 30 mg/l
Test substance: Genamin 12 R 302 D
Reliability: (2) valid with restrictions
04-AUG-2004 (28)

Type: aerobic
Inoculum: activated sludge, industrial, adapted
Concentration: 20 mg/l
Degradation: after 5 day(s)
Result: other
Kinetic:
3 day(s) > 99.99 %
4 day(s) > 99.99 %
5 day(s) > 99.99 %

Method: other
GLP: no
Test substance: other TS

Method: DIN 38412 T.24
Remark: Inoculum: actived sludge, 2 g/l, sewage treatment plant, Gendorf site
Result: Elimination > 99.99 % (mean of three days, determination with GC-MS), hydraulic retention time 4h
Test substance: Genamin LA 302 D, Alkyl(C12-14)dimethylamine
Reliability: (2) valid with restrictions
04-AUG-2004 (29)

Type: aerobic
Inoculum: activated sludge, domestic, non-adapted
Concentration: 20 mg/l
Degradation: after 6 day(s)
Result: other

Method: OECD Guide-line 303 A "Simulation Test - Aerobic Sewage Treatment: Coupled Unit Test"
GLP: no
Test substance: other TS

Remark: Inoculum: 2 g/l, Municipal sewage treatment plant, München II mixed with inoculum from garden soil and surface water
Result: mean elimination 99.6 +/- 0.7% (s = 0.63, n = 6, range: 98.4 - >99.99%) determination with GC-MS, hydraulic retention time 6h
Test substance: Genamin LA 302 D, Alkyl(C12-14)dimethylamine
30-JUN-2003 (30)

3.6 BOD5, COD or BOD5/COD Ratio

3.7 Bioaccumulation

3.8 Additional Remarks

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type: static
Species: Brachydanio rerio (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l **Analytical monitoring:** yes
LC0: .5 -
LC50: .71 - 1
LC100: 1 -

Method: OECD Guide-line 203 "Fish, Acute Toxicity Test"
GLP: yes
Test substance: other TS

Remark: At concentrations of 0.5 - 1 mg/l the test animals showed decrease in activity and startle reflexes, swimming at the bottom, trismus, tail-heavy swimming-posture, spreading-out of gill covers, temporarily increased respiratory rate or sporadically forced respiration, respirectively. After 72 h at 0.1 mg/l, the test animals showed spreading-out of gill covers. At 0.01 mg/l no effects.
Test condition: The stock solution was prepared using ethanol as cosolvent.
Test substance: N,N-Dodecyldimethylamin
Reliability: (2) valid with restrictions
04-AUG-2004 (31)

Type: static
Species: Leuciscus idus (Fish, fresh water)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** no
LC0: .25 -
LC50: .5 - .6

Method: other
GLP: no
Test substance: other TS

Method: Internal testing method (Hoechst AG)
Remark: Test results cannot be validated.
Test substance: (C12-C14)-Alkyldimethylamine
Reliability: (4) not assignable
04-AUG-2004 (23)

4.2 Acute Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** yes
EC0: .16 - .28
EC100: .33 - .57

Method: OECD Guide-line 202
GLP: yes
Test substance: as prescribed by 1.1 - 1.4

Reliability: (1) valid without restriction
Guideline Study

30-JUN-2003 (32)

Species: Daphnia magna (Crustacea)
Exposure period: 48 hour(s)
Unit: mg/l **Analytical monitoring:** yes
EC0: < .06 -
EC50: .083 -
EC100: .16 -

Method: OECD Guide-line 202
GLP: yes
Test substance: as prescribed by 1.1 - 1.4

Reliability: (1) valid without restriction
Guideline Study
30-JUN-2003 (32)

4.3 Toxicity to Aquatic Plants e.g. Algae

Species: Scenedesmus subspicatus (Algae)
Endpoint: growth rate
Exposure period: 72 hour(s)
Unit: µg/l **Analytical monitoring:** no
NOEC: < 2.6 -
EC10: <= 7 -
EC50: <= 23.5 -
EC90 : <= 78.6 -

Method: OECD Guide-line 201 "Algae, Growth Inhibition Test"
GLP: yes
Test substance: as prescribed by 1.1 - 1.4

Reliability: (1) valid without restriction
30-JUN-2003 (33)

Species: Scenedesmus subspicatus (Algae)
Endpoint: biomass
Exposure period: 72 hour(s)
Unit: µg/l **Analytical monitoring:** no
NOEC: < 2.6 -
EC10: <= 4.7 -
EC50: <= 13.3 -
EC90 : <= 38 -

Method: OECD Guide-line 201 "Algae, Growth Inhibition Test"
GLP: yes
Test substance: as prescribed by 1.1 - 1.4

Reliability: (1) valid without restriction
30-JUN-2003 (33)

Species: Scenedesmus subspicatus (Algae)
Endpoint: growth rate
Exposure period: 72 hour(s)
Unit: µg/l **Analytical monitoring:** no
NOEC: 20 -
EC50: 56 -

Method: OECD Guide-line 201 "Algae, Growth Inhibition Test"
GLP: yes
Test substance: other TS

Remark: OECD 201
Test with River Böhme water
Two different natural waters from the rivers "Elbe" and "Böhme" were used as test medium.
The chosen waters originated from a mainly industrial characterised region (Elbe) and a mainly agricultural region (Böhme),
respectively. from a limnological point of view these sampling sites represent typical conditions for rivers of these classification
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (34)

Species: Scenedesmus subspicatus (Algae)
Endpoint: growth rate
Exposure period: 72 hour(s)
Unit: µg/l **Analytical monitoring:** no
NOEC: 20 -
EC50: 92 -

Method: OECD Guide-line 201 "Algae, Growth Inhibition Test"
GLP: yes
Test substance: other TS

Remark: OECD 201
Test with River Elbe water
Two different natural waters from the rivers "Elbe" and "Böhme" were used as test medium.
The chosen waters originated from a mainly industrial characterised region (Elbe) and a mainly agricultural region (Böhme),
respectively. from a limnological point of view these sampling sites represent typical conditions for rivers of these classification
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (34)

Species: Scenedesmus subspicatus (Algae)
Endpoint: growth rate
Exposure period: 72 hour(s)
Unit: µg/l **Analytical monitoring:** no
NOEC: < 10 -
EC50: 14 -

Method: OECD Guide-line 201 "Algae, Growth Inhibition Test"
Test substance: other TS

Remark: OECD 201
OECD-Medium
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (34)

Species: Scenedesmus subspicatus (Algae)
Endpoint: biomass
Exposure period: 72 hour(s)
Unit: µg/l **Analytical monitoring:** no
NOEC: 10 -
EC50: 34 -

Method: OECD Guide-line 201 "Algae, Growth Inhibition Test"
GLP: yes
Test substance: other TS

Remark: OECD 201
Test with River Böhme water
Two different natural waters from the rivers "Elbe" and "Böhme" were used as test medium.
The chosen waters originated from a mainly industrial characterised region (Elbe) and a mainly agricultural region (Böhme),
respectively. from a limnological point of view these sampling sites represent typical conditions for rivers of these classification
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (34)

Species: Scenedesmus subspicatus (Algae)
Endpoint: biomass
Exposure period: 72 hour(s)
Unit: µg/l **Analytical monitoring:** no
NOEC: 20 -
EC50: 56 -

Method: OECD Guide-line 201 "Algae, Growth Inhibition Test"
GLP: yes
Test substance: other TS

Remark: OECD 201
Test with River Elbe water
Two different natural waters from the rivers "Elbe" and "Böhme" were used as test medium.
The chosen waters originated from a mainly industrial characterised region (Elbe) and a mainly agricultural region (Böhme),
respectively. from a limnological point of view these sampling sites represent typical conditions for rivers of these classification
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (34)

Species: Scenedesmus subspicatus (Algae)
Endpoint: biomass
Exposure period: 72 hour(s)
Unit: µg/l **Analytical monitoring:** no
NOEC: < 10 -
EC50: 6 -

Method: OECD Guide-line 201 "Algae, Growth Inhibition Test"
Test substance: other TS

Remark: OECD 201
OECD-Medium
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (34)

4.4 Toxicity to Microorganisms e.g. Bacteria

Type: aquatic
Species: domestic sewage
Exposure period: 24 hour(s)
Unit: mg/l **Analytical monitoring:** no
EC0: 625 - 1000
EC50: 3000 -

Method: ETAD Fermentation tube method "Determination of damage to effluent bacteria by the Fermentation Tube Method"
GLP: no data
Test substance: other TS

Test condition: The stock solution (5 g/l) was prepared at pH 2.
Test substance: N,N-Dodecyldimethylamin
Reliability: (2) valid with restrictions
04-AUG-2004 (22)

Type: aquatic
Species: activated sludge, domestic
Exposure period: 3 hour(s)
Unit: mg/l **Analytical monitoring:** no
EC10: 50 -
EC50: 80 -
EC20 : 60 -
EC80 : 110 -

Method: OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test"
GLP: no
Test substance: other TS

Remark: Deviating from Guideline, 3,5-Dichlorophenol was not used as reference substance.
Test substance: (C12-C14)-Alkyldimethylamine
Reliability: (2) valid with restrictions
04-AUG-2004 (35)

Type: aquatic
Species: domestic sewage
Exposure period: 3 hour(s)
Unit: mg/l **Analytical monitoring:** no
EC50: 27.3 -
EC20 : 5.6 -
EC80 : > 1000 -

Method: OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test"
GLP: yes
Test substance: other TS

Remark: The substance was added directly to diluent water.
Test substance: N,N-Dodecyldimethylamin
Reliability: (2) valid with restrictions
04-AUG-2004 (36)

Type: aquatic
Species: Streptococcus faecalis (Bacteria)
Exposure period: 8 hour(s)
Unit: mg/l **Analytical monitoring:** no data
EC50: 12.8 -

Method: other
GLP: no data
Test substance: other TS

Method: Growth inhibition test
Test condition: 37 °C
Test substance: N,N-Dodecyldimethylamin
Reliability: (4) not assignable
04-AUG-2004 (37)

Type: aquatic
Species: Escherichia coli (Bacteria)
Exposure period: 18 hour(s)
Unit: mg/l **Analytical monitoring:** yes
EC100 : 25 -

Method: other
GLP: no data
Test substance: other TS

Method: Growth inhibtion test
Remark: Streptococcus agalactiae: EC100: 10 mg/l Streptococcus uberis: EC100: 8 mg/l Staphylococcus aureus: EC100: 18 mg/l Klabsiella pneumoniae: EC100: 100 mg/l
Test condition: 37 °C
Test substance: N,N-Dimethyldodecylamine; purity: >98 %
Reliability: (4) not assignable
04-AUG-2004 (38)

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

4.5.2 Chronic Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)
Endpoint: reproduction rate
Exposure period: 21 day(s)
Unit: mg/l **Analytical monitoring:** yes
NOEC: .036 -
LOEC: .108 -
EC50: .31 -

Method: OECD Guide-line 211
GLP: yes

Test substance: other TS

Method: The test method was semi-static. The test solutions were renewed three times per week.
Remark: EC50 for Reproduction 0.31 (0.21-0.44)
Reproduction Test with Natural River Water
As dilution water no fully defined synthetic medium was used but natural occuring river water of the river "Böhme".
The concentration of suspended matter in the river water was approx. 19 mg/l representing typical conditions of german rivers.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (39)

Species: Daphnia magna (Crustacea)
Endpoint: other: immobilisation
Exposure period: 21 day(s)
Unit: mg/l **Analytical monitoring:** yes
NOEC: .108 -
LOEC: .32 -
EC50: .28 -
EC10 : .2 -

Method: OECD Guide-line 211
GLP: yes
Test substance: other TS

Method: The test method was semi-static. The test solutions were renewed three times per week.
Remark: Test with Natural River Water
As dilution water no fully defined synthetic medium was used but natural occuring river water of the river "Böhme".
The concentration of suspended matter in the river water was approx. 19 mg/l representing typical conditions of german rivers.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (39)

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Sediment Dwelling Organisms

Species: other: Caenorhabditis elegans
Endpoint: other: growth, egg production, fertility
Expos. period: 72 other: hours
Unit: mg/kg sediment dw
NOEC: 1620 -
LOEC : 2030 -

Method: other
GLP: no data

Test condition: First stage juveniles of the test species were exposed for 72 h to a mixture of spiked artificial sediment (organic carbon content: 2 %) and a suspension of E. coli. The bacteria served as food for the nematodes. So, the test organisms are exposed to the chemical via sediment, porewater and food.
Test substance: C12-C14 alkyldimethylamine
Reliability: (2) valid with restrictions
04-AUG-2004 (40)

4.6.2 Toxicity to Terrestrial Plants

Species: Avena sativa (Monocotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 320 -
EC50: > 1000 -
EC25 : 526 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
phytotoxic effect: shoot height
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (41)

Species: Avena sativa (Monocotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 100 -
EC50: 700 -
EC25 : 473 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
phytotoxic effect: fresh weight
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (41)

Species: Avena sativa (Monocotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 320 -
EC50: > 1000 -

EC25 : 671 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
phytotoxic effect: seed emergence
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (41)

Species: Brassica napus (Dicotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 10 -
EC50: 120 -
EC25 : 52 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
phytotoxic effect: shoot height
phytotoxic effect: fresh weight
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (41)

Species: Brassica napus (Dicotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 100 -
EC50: 127 -
EC25 : 53 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
phytotoxic effect: fresh weight
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (41)

Species: Brassica napus (Dicotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 320 -
EC50: 586 -
EC25 : 402 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
phytotoxic effect: seed emergence
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (41)

Species: Trifolium pratense (Dicotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 32 -
EC50: 159 -
EC25 : 114 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
phytotoxic effect: shoot height

Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (41)

Species: Trifolium pratense (Dicotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 32 -
EC50: 188 -
EC25 : 129 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
phytotoxic effect: fresh weight
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (42)

Species: Trifolium pratense (Dicotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 320 -
EC50: 237 -
EC25 : 101 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
phytotoxic effect: seed emergence
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (42)

Species: Avena sativa (Monocotyledon)
Endpoint: growth
NOEC: 320 -
EC50: > 1000 -
EC25 : > 1000 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
Type of species : Monocotyledonae: Avena sativa (oat)
Phytotoxic effect : decrease in length
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (42)

Species: Brassica napus (Dicotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 100 -
EC50: 281 -
EC25 : 233 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
Phytotoxic effect : decrease in length
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (42)

Species: Avena sativa (Monocotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 320 -
EC50: > 1000 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
Phytotoxic effect : deformation
Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (42)

Species: Brassica napus (Dicotyledon)
Endpoint: growth
Expos. period: 21 day(s)
Unit: mg/kg soil dw
NOEC: 100 -
EC50: 844 -
EC25 : 275 -

Method: OECD Guide-line 208 "Terrestrial Plants, Growth Test"
GLP: yes
Test substance: other TS

Remark: Analyt. monitor: no
Phytotoxic effect : chlorosis

Test condition: Test medium: Certified LUFA soil No. 2.3 (batch-no. Sp2.35000)
The test item was incorporated into the soil with lyophilised sewage sludge and quartz sand as vehicle in which the seeds were sown.
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (42)

4.6.3 Toxicity to Soil Dwelling Organisms

Species: Eisenia fetida (Worm (Annelida), soil dwelling)
Endpoint: weight
Exposure period: 14 day(s)
Unit: mg/kg soil dw
NOEC: 1000 -

Method: OECD Guide-line 207 "Earthworm, Acute Toxcity Test"
GLP: yes
Test substance: other TS

Remark: The study was conducted under static coditions over a duration of 14 days. The test item was applied once at test begin.
40 test organism with an individual weight of 0,3 to 0,6 g, divided into four replicates, were tested per limit concentration
and control in artifical soil as described by the guidlines.
In the tested limit concetration of 1000 mg/kg no significant mortality
was seen after 14 days of exposure. Also no other effects as pathological symptoms were seen
neither in control group nor in the tested limit concentration
Non standard unit value: NOEC 1000 mg/Kg dw
OECD 207. 1984. ARTIFICIAL SOIL-TEST
Test substance: Genamin LA 302 D
Reliability: (1) valid without restriction
30-JUN-2003 (43)

4.6.4 Toxicity to other Non-Mamm. Terrestrial Species

Species: other: Xyleborus fornicatus
Endpoint: other

Method: other
GLP: no data
Test substance: other TS
Method: brood development test
Remark: 50 ppm (50 mg/kg) incorporated into diet were found to be strongly suppressive to beetle brood development (52 emerging females/tube; control group 38018 females/tube). Insect, beetle
End point: Development
Test condition: 28 +/- 1 °C; 75 +/- 2 % R.H. in complete darkness
Test substance: Dodecyldimethylamine; no information about purity
Reliability: (4) not assignable
04-AUG-2004 (44) (45)

Species: other avian
Endpoint: mortality
Unit: mg/kg bw
LD50 : 101 -

Method: other
GLP: no data
Test substance: other TS

Method: no data
Remark: Estimated LD50 based on food consumption data over a 18 h period.
Species: Agelaius phoeniceus
Test substance: Dodecyldimethylamine
Reliability: (4) not assignable
04-AUG-2004 (46)

4.7 Biological Effects Monitoring

4.8 Biotransformation and Kinetics

4.9 Additional Remarks

5.0 Toxicokinetics, Metabolism and Distribution

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Sex: female
Value: 1450 mg/kg bw

Method: OECD Guide-line 401 "Acute Oral Toxicity"
GLP: yes
Test substance: other TS

Test substance: N,N-Dodecyldimethylamin
17-AUG-2004 (47)

Type: LD50
Species: rat
Sex: male
Value: 1890 mg/kg bw

Method: OECD Guide-line 401 "Acute Oral Toxicity"
GLP: yes
Test substance: other TS

Test substance: N,N-Dodecyldimethylamin
17-AUG-2004 (47)

Type: LD50
Species: rat
Value: 740 mg/kg bw

Method: other
GLP: no data
Test substance: no data

Method: no information
17-AUG-2004 (48)

Type: LD50
Species: rat
Sex: female
Value: 1200 mg/kg bw

Method: other
GLP: no
Test substance: other TS

Method: internal guideline of Hoechst AG
Test substance: (C12-C14)-Alkyldimethylamine
17-AUG-2004 (49)

Type: LD50
Species: rat
Value: 1220 mg/kg bw

Method: other

GLP: no
Test substance: other TS

Method: Description of method in report. Report: US, 1980
Remark: 5 groups of 10 male rats, dosed: 0.6, 0.96, 1.54, 2.47 and 5.0 mg/kg. LD50 = 1.22 g/kg (0.92 - 1.61) Lethargy, diarrhea, ataxia and piloerection were present at all dose levels, and generally persisted to day 2. Body weight and necropsy findings of survivors were generelly normal.
Test substance: Dodecyldimethylamine, distilled; purity: ca. 100 %
17-AUG-2004 (50)

Type: LD50
Species: rat
Value: 1300 - 1500 mg/kg bw

Method: other
GLP: yes
Test substance: other TS

Method: 'Up and Down Method'
Remark: Starting dosing with one male and one female at the estimated LD50. When dead or moribund after 24 hours, a lower dose will be given. If the animal did not die, the next animal was dosed at a higher level. Dosing continued this manner, until a total of 6 animals per sex had been dosed after reversal of the initial outcome. Results with 95 % confidence limits: LD50 males: 1.5 (1.1 to 1.9) g/kg bodyweight LD50 females: 1.3 (1.0 to 1.7) g/kg bodyweight
Test substance: Alkyl(C12-14)dimethylamine; purity: ca. 100 %
17-AUG-2004 (51)

5.1.2 Acute Inhalation Toxicity

5.1.3 Acute Dermal Toxicity

5.1.4 Acute Toxicity, other Routes

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: rabbit
Result: corrosive
EC classificat.: highly corrosive (causes severe burns)

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
GLP: yes
Test substance: other TS

Remark: Exposure time: 3 min and 4 h; must be labelled according Directive 83/467/EEC with C and R 35

Test substance: (C12-C14)-Alkyldimethylamine
17-AUG-2004 (52) (53)

Species: rabbit
Result: corrosive
EC classificat.: corrosive (causes burns)

Method: Draize Test
GLP: no
Test substance: other TS

Remark: Method: Patch test on the abraded and intact skin of 12 albino rabbits. Application of 0.5 ml under surgical patch (ixi inch) for 24 hours. Evaluation by method of Draize (J. Pharmacol. 82 (1944) 377-390) at removal of patches and 48 hours later.
No differences between abraded and intact skin.
Test substance: Alkyl(C12-14)dimethylamine; purity: ca. 100 %
17-AUG-2004 (54)

Species: rabbit
Result: highly irritating
EC classificat.: irritating

Method: other
GLP: no
Test substance: other TS

Method: Hoechst AG internal directive
Remark: Must be labelled according Directive 83/467/EEC with C and R 35
Test substance: (C12-C14)-Alkyldimethylamine
16-DEC-2002 (55)

5.2.2 Eye Irritation

Species: rabbit
Result: moderately irritating
EC classificat.: irritating

Method: other
GLP: no
Test substance: other TS

Method: Hoechst AG internal directive
Test substance: (C12-C14)-Alkyldimethylamine
17-AUG-2004 (56)

5.3 Sensitization

5.4 Repeated Dose Toxicity

Species: rat **Sex:** male/female
Strain: Sprague-Dawley
Route of administration: gavage
Exposure period: 28 days
Frequency of treatment: daily
Post exposure period: no data
Doses: 0, 50, 150, 300 mg/bw/d
Control Group: yes
NOAEL: 50 mg/kg

Method: OECD Guide-line 407 "Repeated Dose Oral Toxicity - Rodent: 28-day or 14-d Study"
GLP: yes
Test substance: other TS

Remark: 5 animals/sex/group
Result: 300 mg/kg was within lethal range (3 of 5 females died); slight effects (rubbing of snouts in bedding material) at 150 mg/kg)
Test substance: Dodecyldimethylamin (99.8 %)
16-DEC-2002 (57)

5.5 Genetic Toxicity 'in Vitro'

Type: Ames test
Metabolic activation: with and without
Result: negative

Method: OECD Guide-line 471
GLP: yes
Test substance: other TS

Remark: Test system: Salmonella typhimurium TA 98, TA 100, TA 1535, TA 1537, TA 1538
Test System: sonstige
Test substance: N,N-Dodecyldimethylamin
17-AUG-2004 (58)

Type: Ames test
Metabolic activation: with and without
Result: negative

Method: OECD Guide-line 472
GLP: yes
Test substance: other TS

Remark: Test System: Escherichia coli WP2uvrA
Test System: sonstige
Test substance: N,N-Dodecyldimethylamin
17-AUG-2004 (58)

5.6 Genetic Toxicity 'in Vivo'

Type: Micronucleus assay
Species: mouse **Sex:** male/female
Strain: NMRI
Route of admin.: oral unspecified
Exposure period: twice at an interval of 24 h
Doses: 0, 120, 400, 1200 mg/kg bw

Method: OECD Guide-line 474 "Genetic Toxicology: Micronucleus Test"
GLP: yes

Remark: 5 animals/sex/group
Test substance: other TS
Test substance: Genamin LA 302 D (100 %)
16-DEC-2002 (59)

5.7 Carcinogenicity

5.8.1 Toxicity to Fertility

Type: other
Species: rat
Sex: male/female
Strain: Sprague-Dawley
Route of administration: gavage
Frequency of treatment: daily
Premating Exposure Period
male: 14 d
female: 14 d
Duration of test: see freetext
Doses: 0, 50, 150, 300, 450 mg/kg/d
Control Group: yes

Method: OECD combined repeated dose and reproductive/developmental toxicity screening test
GLP: yes
Test substance: other TS

Remark: Test duration: Males: 14 d prior mating and 14 d during mating Females: 14 d prior mating, during mating, pregnancy and lactation period
Type of value: Reproduction/development Toxicity Sreening Test
16-DEC-2002 (60)

5.8.2 Developmental Toxicity/Teratogenicity

5.8.3 Toxicity to Reproduction, Other Studies

5.9 Specific Investigations

5.10 Exposure Experience

5.11 Additional Remarks

Type: other

Remark: Rat (Sprague-Dawley), male/female, 0 or 12 mg nitrosomethyldodecylamine (reaction product of diemthyldodecylamine with nitrous acid), p.o., 2 times/week, 50 weeks Result: Bladder-, lung- and one oesophagus tumour. The males are more sensitive as the females.

16-DEC-2002 (61)

Type: other

Remark: Rat (Sprague-Dawley), male/female; 15 animals/sex/group, control: 0.2 % Na-nitrit, 2 years or 0.18 dimethyldodecanamine + 0.2 % Na-nitrit in the drinking water, 5 days/week, 80 weeks Results: Survival rate and tumor incidence of the most tumours were in the same range as those of the control. The higher incidence of bladder-tumours (control 0/56; females 1/9; males 2/15) is for the opinion of the authors an effect of the treatment, because the habend been seen spontaneous before. They suppose that in vivo nitrosomethylamine was formed, which causes the significant incidence of maligne tumours.

16-DEC-2002 (62)

(1) Kenndatentabelle über Fettamine und Folgeprodukte der Hoechst AG, Verkauf TH (Januar 1980)

(2) Hoechst AG (1993): Interne Mitteilung des Geschäftsbereich E, TH/TVS (14.06.1993)

(3) Clariant GmbH (1997): Schriftliche Mitteilung vom 07.07.1997

(4) Clariant GmbH (1998): Schreiben Div. SUR vom 04.05.1998

(5) Clariant GmbH (1998): EC safety data sheet Genamin LA 302 D (08.10.98)

(6) Hoechst AG (1992): Personal communication, Production Division

(7) Hoechst AG (1988): Einstufungsbegründung WGK, Abt. UCV (25.07.1988)

(8) Hoechst AG (1991): Einstufungsbegründung nach TA-Luft der Abt. UCV (14.03.1991)

(9) Clariant GmbH (1999): Exposure data for OECD SIAR (C12-C14)-alkyldimethylamine, 03.05.1999

(10) Dreisbach (1961): Physical Properties of Chemical Compounds-III, Advances in Chemistry Series No. 29, Washington, DC, American Chemical Society, 357, 359, 360, 382

(11) TRC Thermodynamic tables a-9150

(12) Hoechst AG (1995): Sicherheitsdatenblatt Genamin LA 302 D (28.02.95)

(13) Ullmann's Encyclopedia of Industrial Chemistry (1985): Vol. A2, 19, 25

(14) Windholz (1983): The Merck Index, 10th ed. Rahway, NJ, Merck & Co., Inc., 1381-1382

(15) Hoechst AG (1993): Interne Berechnung vom 07.05.1993

(16) Hoechst AG (12.03.1991): Interne Mitteilung der Abt. Produktentwicklung GB-C, Ökologie I

(17) Clariant GmbH (1999): Calculation of Log Kow, SRC LOGKOW v1.51

(18) Clariant GmbH (1999): Calculation of water solubility from Log Kow, SRC WSKOW v1.33

(19) Clariant GmbH (1999): Calculation of pKa (pKalc 3.2 Compudrug)

(20) Hoechst AG (1994): Unveröffentlichte Untersuchung OC 103-93

(21) Akzo Nobel: Unpublished results

(22) Hoechst AG (1991): Unveröffentlichte Untersuchung (W 88-062)

(23) Hoechst AG (1978): Unpublished results (4/78)

(24) Hoechst AG (1992): Unveröffentl. Unters. (92-0067-R1)

(25) Ministry of International Trade and Industry (MITI) (1992): Biodegradation and bioaccumulation data of existing chemicals based on the Chemical Substances Control Law (CSCL), Japan. Chemicals Inspection and Testing Institute (CITI) (ed.); Japan Chemical Industry Ecology - Toxicology and Information Center 1-27, 2-33

(26) Akzo Nobel Chemical (1991): CRL F91121 (28.02.1991)

(27) Akzo Nobel Chemical (1992): CRL R91068 (28.02.1992)

(28) Yoshimura, Machida, Masuda (1980): JAOCS 7, 238-241

(29) Clariant GmbH (1999): Unveröffentlichte Untersuchung der InfraServ Gendorf, Fachbereich Umwelt, Abbau von Genamin LA 302 D, 9.02.99

(30) Clariant GmbH (2000): Unveröffentl. Untersuchung der InfraServ Gendorf, FB Umwelt, Abbau von Genamin LA 302 D, (00/013-02), 9.08.00

(31) Hoechst AG (1988): Unveröffentlichte Untersuchung (88.0432)

(32) Hoechst AG (1994): Unveröffentlichte Untersuchung 93-0161-32

(33) Hoechst AG (1995): Unveröffentl. Unters. (93-0161-22)

(34) Clariant GmbH (2000) : Project-No. 000901CK Dr. U. Noack-Laboratorium für Angewandte Biologie (04.10.2000)

(35) Noack Laboratorium (1989): Unpublished results (8.683)

(36) Hoechst AG (1991): Unveröffentlichte Untersuchung (91-0022-01)

(37) Bass, Powers, Dillingham (1976): J. Pharm. Sciences 65, 1525-1527

(38) Culler, Bitman, Thompson (1979): J. Dairy Sci. 62, 584-595

(39) Clariant GmbH 2001: (Project-No. 001114CK) Dr. U. Noack Laboratorium für Angewandte Biologie (17.01.2001)

(40) BSB 2000: Toxicity of sodium tetrapropenyl benzene sulfonate, cocos dimethylamine, di hardened tallow dimethyl ammonium chloride and tallow alkylamine on the nematode Caenorhabditis elegans in artificial sediment.

(41) Clariant GmbH (2001): (Study-No. TNC75353, Dr. U. Noack-Laboratorium für angewandte Biologie) (03.05.2001)

(42) Clariant GmbH (2001): (Study-No. TNC75353, Dr. U. Noack-Laboratorium für angewandte Biologie (03.05.2001)

(43) Clariant GmbH (2000) : Dr. U. Noack Laboratorium für Angewandte Biologie Study-No. RRA75351 (01.11.2000)

(44) Sivapalan, Shivanandarajah (1977): Ent. exp. & appl. 21, 1-8

(45) Sivapalan, Shivanandarajah (1977): Ent. exp. & appl. 22, 274-279

(46) Schafer et al. (1983): Arch. Environ. Contam. Toxicol. 13, 355-382

(47) Hoechst AG (1988): Unveröffentl. Unters. (Ber.-Nr. 88.0459)

(48) Clin. Memo. Econ. Poisons (1956): 1; zitiert in: RTECS (April 1991)

(49) Hoechst AG (1978): Unveröffentl. Unters. (Ber.-Nr. 78.0496)

(50) Akzo Nobel Chemical (1980): Study report (19.08.1980)

(51) Akzo Nobel Chemical (1984): 84105D/AKZ (24.02.1984)

(52) Hoechst AG (1988): Unveröffentl. Unters. (Ber.-Nr. 88.0427)

(53) Hoechst AG (1989): Unveröffentl. Unters. (Ber.-Nr. 89.0679)

(54) Akzo Nobel Chemical (1979): R 6011 (March 1979)

(55) Hoechst AG (1978): Unveroeffentlichte Untersuchung (78.0497)

(56) Hoechst AG (1978): Unveröffentl. Unters. (Ber.-Nr. 78.0497)

(57) Hoechst AG (1995): Unveröffentlichte Untersuchung (LPT-Report No. 8767/94)

(58) Hoechst AG (1988): Unveröffentl. Unters. (Ber.-Nr. 88.0373)

(59) Clariant GmbH (1999): Unveröffentlichte Untersuchung (99.0074)

(60) Hoechst AG (1995): Unveröffentlichte Untersuchung (LPT-Report No. 8768/94)

(61) Lijinsky, Taylor (1975): Cancer Res. 35, 958-961

(62) Lijinsky, Taylor (1977): Fd. Cosmet. Toxicol. Vol. 15, 269-274