SUBSTANCE EVALUATION REPORT

Public Name: 2-(phenylmethoxy) naphthalene

EC Number(s): 405-490-3

CAS Number(s): 613-62-7

Submitting Member State Competent Authority: Ministry of Environment of the Czech Republic, Vršovická 1442/65, Praha 10, 100 10

Year of evaluation (as given in the CoRAP): 2012

VERSION NUMBER: 2.0 DATE: 16 December 2015

Conclusions of the most recent evaluation step	Tick relevant box(es)
Concern not clarified; Need to request further information from the Registrant(s) with the draft decision	
Concern clarified; No need of further risk management measures	
Concern clarified; Need for risk management measures; RMO analysis to be performed	X
Other:	

Executive summary

Grounds for concern

The substance was included into CoRAP according to Art. 44(1)(a), based on the risk assessments performed by the German UBA with conclusion that the substance may cause long-term effects in the environment.

2-(phenylmethoxy) naphthalene is NONS substance and previous assessments have been carried out for tonnages up to 100 tonnes and conclusions on the assessments were not consistent. Consequently it led to a conclusion that the long term effects of the substance cannot be excluded.

As sufficient information was not provided in the aggregated dataset on long-term aquatic toxicity, the concern could not be confirmed or refuted.

From the information provided on bioconcentration it was not possible to make a conclusion about the validity of the test as the validity criteria were not explicitly evaluated and the overall information provided was not sufficient to conclude. Thus an additional concern occurred about unequivocal decision on PBT properties and consequently an additional concern for occupational exposure was noted.

Procedure

All of the data available on fate in environment, aquatic toxicity and toxicity to reproduction were studied.

After evaluation of existing information which relate to the main grounds of concern, it was concluded that the concern cannot be solved on the basis of the present data and it is necessary to clarify chronic aquatic toxicity and potential for bioaccumulation.

A draft decision to request further information was sent to registrants on either 4 April 2013 or 26 April 2013.

Comments on the draft decision were received from the lead registrant of the newly formed SIEF and indicated that the most important requested data already exists but it was not yet submitted in any of the registration dossiers.

The Czech Competent Authority communicated by e-mail with representative of a lead registrant on behalf of newly established SIEF and an agreement was reached by end of July 2013 that a lead registration will be submitted with all available data. A lead registration dossier was submitted on 20 August 2013. The new data was thoroughly evaluated by the Czech MSCA and the conclusion was made that the decision-making process can be terminated and the Substance evaluation concluded.

Conclusions

Evaluation of existing information

A valid long-term test on aquatic toxicity was not available. One of tests provided in the aggregated dataset was a long-term test on *Daphnia* which indicates that the substance is not detected at the end of the exposure period, so in that case the validity of the test should be reconfirmed.

A valid long-term test on fish was not available as well. Provided test according to OECD 204 (Fish, Prolonged Toxicity Test: 14-Day Study) is not considered as suitable long-term test. Chronic toxicity can be proven only on early stages of fish and there was only data for toxicity to adult fish in registrant´s dossier. It could not be determined from the available data if fish were likely to be less sensitive than *Daphnia* and a fish early life stage test was requested.

The provided OECD 305E test on bioconcentration indicated using of dispersants without any information about its content, information about fulfilment of validity criteria and other test conditions to a sufficient extent. Therefore an adopted version of test OECD 305 was requested.

Overall data did not enable assessment of the toxicity properties of the substance as the robust study summaries on reproductive toxicity in the initial dossiers were not sufficient for the assessment. Also simulation test was required as necessary for confirming whether the P or vP criterion is met.

The evaluation of P/vP criterion based on QSAR values and existing study results reported in the registration dossiers:

QSAR values

Results from BIOWIN 3 model indicate values between 2.2 and 2.7. It consequently requires more degradation relevant information in relation to the PBT testing strategy described in the ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment.

Study results

The Biochemical Oxygen Demand BOD5 (EU Method C.5) and the Chemical Oxygen Demand COD (EU Method C.6) were determined. The substance is non-biodegradable based on the ratio BOD5/COD (BOD5/COD = 0).

The substance was further investigated for its biodegradability in:

a) Ready Biodegradability test

- EU C.4-C Determination of the "Ready" Biodegradability - Carbon Dioxide Evolution Test
- OECD 301D Ready Biodegradability test (7% in 28 days; O2 consumption)

b) Inherent Biodegradability tests

- EU C.9 Biodegradation: Zahn-Wellens Test
- OECD 302 C Inherent Biodegradability: Modified MITI Test (II)

The results of all experiments (predominantly 0-1% degradation) indicate that the substance is neither ready biodegradable or inherently biodegradable.

Evaluation of new information submitted by the Registrant(s) in response to a SEv draft decision

The lead registrant included a waiver for freshwater/sediment simulation testing and concluded that the substance is very persistent vP.

The submitted FELS test demonstrated the long-term effects on the early stages of fish, NOEC lower than water solubility was derived so finally based on information from this test the initial concern was confirmed.

Provided OECD 305E Bioconcentration test has been submitted with sufficient detail of the study conditions, which now enables the confirmation of its validity.

Consequently, it was possible to make a conclusion on the PBT status of substance and to examine the extent of exposure.

As a result of all submitted tests it was concluded that the substance is not considered as PBT. Furthermore the Czech MSCA concluded, based on the examination of the exposure assessment (provided in Confidential Annex), that there is no concern for long term environmental effects, if the substance is self-classified as Aquatic Chronic 1 and RMMs recommended by the registrants for industrial sites, which prevent direct or indirect exposure to soil and sediment, are in place.

The eMSCA also concludes that there is no concern related to the subsequent life cycle stages handling the product with substance as the substance in the final products is used in low concentration up to 1% and is bound to the paper surface by a polymer layer.

Statement of reasons

Information on biodegradability, long-term toxicity effects and bioaccumulation was required in a draft decision in order to enable to assess the PBT properties of the substance. Subsequently it was followed by dossier update and the information was received even without a formal decision.

<u>Persistency</u>

The results of all experiments (0-1% degradation) indicate that the substance is neither ready biodegradable or inherently biodegradable. The degradation below 20% in the inherent biodegradability test can provide sufficient information to confirm persistence.

Although for final decision on persistency of the substance the simulation studies are the only tests that can provide a definitive degradation half-life which can be compared directly to the persistency criteria, the sediment simulation degradation testing is not warranted anymore as the substance is considered by registrants as very persistent.

<u>Bioconcentration</u>

The registrants have a specific OECD 305E test for determining the bioaccumulation potential of the substance. The Czech MSCA had some concerns about the validity of this test:

• using of dispersants (without information about amount)

• missing declaration of test validity.

Therefore, the B criterion was initially evaluated by using of screening data: measured Kow values provided in the registration dossiers and QSAR values (log Kow from EPI SUITE is 4.96 and from TOPKAT 6.2 is 4.74). QSAR value of BCF used for comparison with B criterion is circa 870 and therefore according to criterion „not B“.

As the provided test OECD 305E indicated using of dispersants without any information about its content, information about fulfilment of validity criteria and other test conditions to a sufficient extent, it was concluded that would be better to determine bioaccumulative potential according to current version of test OECD 305 adopted in 2012.

After the registrant's comments the information about the amount of dispersant was finally provided and it conforms to the requirement of adopted test (Details in corresponding section on Aquatic bioaccumulation). Actually only 5.56 mg/L dispersant was used in the test, which is far from allowed content 100 mg/L.

After submission of the lead registrant dossier, provided OECD 305E Bioconcentration test has been submitted with information which still did not enable the confirmation of its validity. It was still necessary to request a full study report to examine test conditions on validity criteria and overall conditions. The study report was thoroughly examined by the Czech MSCA and compared with the approach which is laid down in adopted version guideline.

In the end it could be concluded that there is sufficient information to conclude that the substance is not bioaccumulative or very bioaccumulative according to REACH Annex XIII.

Aquatic toxicity

No suitable long-term test on fish was available in the registration dossiers.

The test performed according to OECD 204 (Fish, Prolonged Toxicity Test: 14-Day Study (OECD 1984)) could not be considered as suitable long-term test as it is only prolonged acute study with fish mortality as the major endpoint to be examined.

Chronic toxicity can be proven only on early stages of fish while there was only information on adult fish available in the registration dossiers. Therefore it could not be determined from available data if fish is less sensitive than *Daphnia*. There was therefore a need to require an alternative test on sensitive life-stages (juveniles, eggs, larvae) of fish.

The alternative fish early life stage test (FELS) is considered as the most sensitive of the fish tests. It covers several sensitive life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and it is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation. The NOEC value from long-term toxicity testing on fish according to FELS test can be used directly for PNEC assessment.

The FELS test was requested to unequivocally confirm the T criterion in PBT assessment and as the long-term effects could not be ruled out based on existing studies.

The registrant´s comments showed that the required test was already available. After submission of the lead registrant dossier the submitted FELS test demonstrated the long-term effects on the early stages of fish and based on information from this test the initial concern was confirmed. The NOEC was derived lower than water solubility and used for deriving a PNEC.

Consequently, it was also possible to reach a conclusion on the potential PBT properties of the substance and to examine the extent of exposure.

Exposure assessment

An exposure assessment was required in order to clarify the concern related to exposure and high aggregated tonnage of the substance.

The concerned registrants were requested to provide information which relates to the most recent situation on tonnage produced or imported into the relevant markets in the Member States from the individual registrants, estimates or measurements of occupational exposure under the current situation and conditions.

During substance evaluation, it came to light that some registrants had already ceased production and it was confirmed by them immediately after receipt of the draft decision. Therefore the actual tonnage was much lower than estimated when the substance was included in CoRAP.

Provided exposure assessment was revised (examination provided in Confidential Annex), which demonstrated no concern of the substance even using the highest aggregated tonnage, if the substance is self-classified as Aquatic Chronic 1 and the RMMs recommended by the Registrants for industrial sites, which prevent direct or indirect exposure to soil and sediment, are in place.

The Czech MSCA also concludes that there is no concern related to the subsequent life cycle stages handling of the product with substance as the substance in the final products is used in low concentration up to 1% and is bound to the paper surface by a polymer layer.

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TABLES

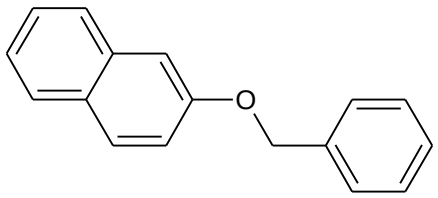
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	**2-(phenylmethoxy)naphthalene**
EC number:	405-490-3
EC name:	2-(phenylmethoxy)naphthalene
CAS number (in the EC inventory):	Not available
CAS number:	613-62-7
IUPAC name:	2-(phenylmethoxy)naphthalene
Index number in Annex VI of the CLP Regulation	603-128-00-0
Molecular formula:	C17H14O
Molecular weight range:	234 g/mol
Synonyms:	BETA-NAPHTYLBENZYL ETHER (NBE) BENZYL-2-NAPHTHYL-ETHER (BNE)

Structural formula:



1.2 Composition of the substance

Stated in Confidential Annex

1.3 Physico-chemical properties

The substance is white and odourless powder under normal conditions with very low vapour pressure (0.000045 Pa at 25°C).

According to the evaluated concerns is water solubility one of the most important properties. The reliable value is considered to be 0.027 mg/L determined by column elution method with analytical HPLC extraction and with information about pH 6.74-6.93 at 20°C.

The log Kow of 5 was experimentally determined at 21 °C and experimental value log Koc 4.29 at 30°C using HPLC analysis.

2 MANUFACTURE AND USES

2.1 Quantities

Aggregated tonnage (per year)

1000 – 10000t

2.1.1 Manufacturing processes

Not relevant for this evaluation.

2.2 Identified uses

2.2.1 Uses by workers in industrial settings

The substance is used in thermal paper coatings. It is used as such or in a mixture in exposure scenarios for processes formulation of mixture for coating, coating itself and handling of thermal paper in industrial sites.

2.2.2 Use by professional workers

Not relevant for this evaluation.

2.2.3 Uses by consumers

Uses by consumers cover handling with products made from thermal paper.

2.3 Uses advised against

No information available.

2.3.1 Uses by workers in industrial settings advised against

No information available

2.3.2 Use by professional workers advised against

No information available

2.3.3 Uses by consumers advised against

No information available

3 CLASSIFICATION AND LABELLING

3.1 Harmonised Classification in Annex VI of the CLP Regulation

Index No: 603-128-00-0
Chemical name: 2-(phenylmethoxy)naphthalene
EC No: 405-490-3
CAS No: 613-62-7
Classification: Aquatic Chronic 4
Hazard statement:
H413: May cause long lasting harmful effects to aquatic life.

3.2 Self classification

Classification: Aquatic Chronic 1
Hazard statement:
H410: Very toxic to aquatic life with long lasting effects, M-factor 10
Self-classification based on results from long term Fish, Early-Life Stage (FELS) Toxicity Test OECD Test Guideline 210.

4 ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation

4.1.1 Abiotic degradation

4.1.1.1 Hydrolysis

No hydrolysis test has been performed as the study is scientifically unjustified.

4.1.1.2 Phototransformation/photolysis

4.1.1.2.1 Phototransformation in air

In aggregated dataset a short half-life in the atmosphere DT50 ca 0.61 h was determined by calculation method, confirming that photochemical degradation is expected to be rapid in air.

4.1.1.2.2 Phototransformation in water

No data available.

4.1.1.2.3 Phototransformation in soil

No data available.

4.1.2 Biodegradation

4.1.2.1 Biodegradation in water

4.1.2.1.1 Estimated data

No data available.

4.1.2.1.2 Screening tests

The Biochemical Oxygen Demand BOD5 (EU Method C.5) and the Chemical Oxygen Demand COD (EU Method C.6) were determined. The substance is non-biodegradable based on the ratio BOD5/COD (BOD5/COD = 0).

The substance was further investigated for its biodegradability in:

Ready Biodegradability test

- EU C.4-C Determination of the "Ready" Biodegradability - Carbon Dioxide Evolution Test
- OECD 301D Ready Biodegradability (7% in 28 days, O2 consumption)

Inherent Biodegradability test

- EU C.9 Biodegradation: Zahn-Wellens Test
- OECD 302 C Inherent Biodegradability: Modified MITI Test (II)

The results of all experiments (predominantly 0-1% degradation) indicate that the substance is neither ready biodegradable or inherently biodegradable.

The degradation below 20% in the inherent biodegradability test provides sufficient information to confirm persistence.

4.1.2.1.3 Simulation tests (water and sediments)

After examining all the information available on bioaccumulation the Czech MSCA concluded that the criterion for B/vB was not met and for this reason the examination of persistency criterion is not necessary to be exhaustive.

Although simulation tests are the only ones to prove actual degradation half-lives for direct comparison with PBT criteria (OECD 308 or 309) but rather it is a case when it is necessary to try excluding persistence of the substance.

However, especially in this decision are taken into account information on measures to prevent exposure of aquatic compartment and the possibility for direct and indirect exposure to soil and sediment.

Based on the available information measures at industrial sites effectively preventing exposure of aquatic compartment were implemented since the substance is self-classified by registrants as Aquatic Chronic 1.

Direct exposure of soil or sediment is not expected to occur and sludge seems not to be spread on soil but it is incinerated so indirect exposure does not exist as well.

Due to Koc value the potential for long-range transport is very limited in aquatic environment. The substance in the product life stage is bound to the matrix.

As a result there it is no longer necessary to require simulation tests on the biodegradation of the test substance in water and sediments to clarify the initial concern for substance evaluation.

4.1.2.1.4 Summary and discussion of biodegradation in water and sediment

The substance is not readily biodegradable. Based on all biodegradation tests in water and its physico-chemical properties the substance is considered as persistent by registrants. According to information on emissions, experimental simulation tests are unlikely to provide data which could significantly change the risk assessment.

Due to the high adsorption potential, if any residual substance exists, it will be adsorbed on the sludge in a sewage treatment plant which is incinerated.

4.1.2.2 Biodegradation in soil

No data available.

According to the available information, measures at industrial sites effectively preventing exposure of aquatic compartment were implemented since the substance is self-classified by registrants as Aquatic Chronic 1.

Direct exposure to soil or sediment is not expected to occur and sludge appears not to be spread on soil but it is incinerated so indirect exposure does not exist as well.

The substance in the product life stage (if it is disposed to dedicated landfill sites) is bound to the matrix and is not released.

4.1.3 Summary and discussion on degradation

Abiotic degradation

The substance does not undergo hydrolysis process but can be rapidly degraded by photolysis in air. No data are available about photodegradation in water or soil.

Biotic degradation

The substance is not readily biodegradable and it is considered as persistent. According to information on emission new simulation studies in water and sediment or in soil are not deemed necessary due to a very small probability to obtain data which could significantly change the risk assessment.

4.2 Environmental distribution

4.2.1 Adsorption/desorption

Adsorption to solid particles in environment is expected and Koc 4.29 determined by HPLC estimation method indicates immobility of substance in soil and sediment.

4.2.2 Volatilisation

Based on calculated Henry's law constant the substance will not evaporate from the water surface.

4.2.3 Distribution modelling

Data from aggregated dossier by calculation according to Mackay, Level I indicate distribution of 93% to the soil and sediment.

4.2.4 Summary and discussion of environmental distribution

For the substance are expected following distribution mechanisms: the substance will not evaporate from the water surface and preferably will be distributed to the soil and sediment.

4.3 Bioaccumulation

4.3.1 Aquatic bioaccumulation

Bioaccumulative potential was determined by specific test OECD 305E (Bioaccumulation: Flow-through Fish Test, freshwater, *Lepomis macrochirus*).

Steady-states were reached rapidly and depuration was rapid as well with half-lives up to 15 hours. But for poorly soluble substance in range 0.01-0.1 mg/L the test may not provide a reliable BCF. A statement about the validity was missing in the provided tests and there was information about using of dispersant without any details.

The information submitted by registrants was not sufficient to assess, whether the submitted test is acceptable. Regarding to the missing data it was not possible to assess compliance with validity criteria. Also according to current approach to dispersants was not possible to decide if using of dispersant was correct in this study.

Therefore within substance evaluation the competent authority asked for the full study report and detailed examination was conducted to draw conclusions about the validity of the results of bioaccumulation potential based on this study according to current approaches.

Since the full report data were reported in quite sufficient detail about test conditions it allowed comparing with validity criteria as described below.

Considering the method of implementation of provided OECD 305E it is concluded that BCF value based on lower concentration is applicable for CSA.

The test concentrations:

The concentrations to be used in the study and determining actual dissolved concentrations are one of the critical parameters.

Although one test concentration was above the measured water solubility, the other is lower than the water solubility of the substance.

The test was initially designed for non-polar substances and therefore using of only one concentration could be sufficient because of no concentration effects are expected (OECD 305 adopted (2012)). Since there are very similar depuration times (11-15 hours) and radioactivity levels were low at the end of depuration period, the influence of concentration is decreased.

The concentration of the test substance in the chambers was maintained within ± 20% of the mean of the measured values during the uptake phase as concentration criterion requires.

The test water may have had an effect on the solubility of the test substance. Test conditions are 21°C, pH 7.8-8.0 and substance solubility in pure water was determined at 20°C and pH 6.8. Maximum dissolved concentration of the substance thus could be lower than from the water solubility test as there is typically a difference between solubility in pure water and testing media (OECD No.23).

14C-labeled substance was used as it is recommended when expecting any problems with the identification of substances in the samples. Lower concentration is applicable also because of LOD is the order of magnitude of ppb units.

The actual concentrations of dissolved substance were investigated. There was no excessive amount of particulate matter, otherwise the test concentrations of centrifuged fractions would also had been measured – as was declared in the Study plan.

The use of a minimal amount of dispersant enabled preparation of a clear solution and its amount was below the critical micellar concentration and its concentration was the same in all solutions.

The final content of Tween80 (this used dispersant is still allowed option in adopted OECD 305(2012) guideline) in application solution was 0.002% which corresponds to 5.56 mg/L thus still under the maximum recommended level 100mg/L for cases where using of dispersants is necessary.

In this case it is unlikely that dispersant significantly influences the maximum dissolved concentration of the test substance in the medium.

The critical micelle concentration of Tween80 in pure water is reported as 0.012 mM corresponds to the concentration 7.26 mg/L (0,012*Molecular Weight of Tween80) which is higher than 5.56 mg/L in the final application solution in study therefore precipitation of substance in the container and reducing the bioavailability of the substance is rather unlikely.

Other validity criteria (temperature, dissolved oxygen, mortality) were fulfilled except short deviation of temperature in depuration phase which is considered as less significant than in uptake phase as several publications about influence of parameters do not even mention examination in depuration phase but on contrary addressed the uptake phase.

Overview of examined conditions related to overall conditions of the study is part of the Confidential Annex.

4.3.2 Terrestrial bioaccumulation

The study according to OECD 207 with earthworms confirmed that worms generally have more developed system for the degradation of xenobiotic and result in BCF >1000mg/kg.

4.3.3 Summary and discussion of bioaccumulation

Aquatic bioaccumulation

The value BCF of 180 was determined in a GLP guideline bioconcentration study according to OECD 305E with *Lepomis macrochirus* exposed to substance concentration 0.0078 mg/L.

The test is considered as acceptable and result indicates that the substance did not significantly bioaccumulate in fish.

4.4 Secondary poisoning

Although the substance is persistent in the environment, the B criterion was not met and substance is not classified as STOT RE category 1 or 2 (H372 “Causes damage to organs through prolonged or repeated exposure, H373 “May cause damages to organs through prolonged or repeated exposure”) toxic for reproduction category 1A, 1B or 2 (H360F “May damage fertility”, H360D “May damage the unborn child”, H360f “Suspected of damaging fertility”, H361d “Suspected of damaging the unborn child”, H362 “May cause harm to breast-fed children”) thus secondary poisoning is unlikely.

5 HUMAN HEALTH HAZARD ASSESSMENT

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1 Non-human information

Absorption

No signs of systemic toxicity were observed in an acute oral and dermal toxicity study.

It was concluded, that dermal absorption is limited based on physical-chemical properties. Uptake is likely to be low due to low solubility, but also the highly lipophilic substances (log Kow from 4 up to 6) readily penetrate to the lipid rich stratum corneum where they can persist but the stratum corneum can be sloughed off.

Generally mechanism of transportation based on physical-chemical properties is presumed to be the incorporation of the lipophilic substance into the micelles and for respiratory absorption as well.

But for poorly water-soluble dusts the direct respiratory absorption is limited by the rate at which the particles dissolve into the mucus which in addition could be subsequently coughed or sneezed out or swallowed (particles > 5 μm are most likely be settled in the nasopharyngeal region. For example lead registrant reports in the dossier only 1.55 % are smaller than 5 μm).

But as no data are available for respiratory absorption a default value of 100% is used. In industrial uses after delivery the substance is emptied in dedicated sites and subsequently transported under closed conditions. In addition, when taken into account vapour pressure, the inhalation exposure appears not to be relevant.

Other phases of its lifecycle within the body are not addressed. Rates of absorption were examined due to revision of provided exposure assessment.

5.1.2 Human information

No data available.

5.1.3 Summary and discussion on toxicokinetics

The results of repeated dose toxicity studies and reproduction studies were used for evaluation of toxicokinetics by registrants taking into account the systemic effects at the hepatic level.

It is concluded that bioaccumulation potential exists based on substance properties (water solubility and log Kow).

It is also assumed that metabolism undergo Phase I reactions under the action of metabolic enzymes and process is finalized predominantly by renal and faecal excretion.

Based on those data following values were assumed for risk assessment - 100% absorption for inhalation and oral route (default values) and 10% by dermal route based on log Kow and low substance solubility.

5.2 Acute toxicity

5.2.1 Non-human information

5.2.1.1 Acute toxicity: oral

The study on acute toxicity after oral administration result in LD50 ≥ 5000 mg/kg bw based on test substance.

5.2.1.2 Acute toxicity: inhalation

For poorly water-soluble dusts the direct respiratory absorption is limited by the rate at which the particles dissolve into the mucus which in addition could be subsequently coughed or sneezed out or swallowed (particles > 5 μm are most likely be settled in the nasopharyngeal region).

In addition, when taken into account vapour pressure the inhalation exposure does not appear to be a relevant route of exposure.

5.2.1.3 Acute toxicity: dermal

The results of studies on acute toxicity after dermal administration result in LD50 > 2000 mg/kg bw based on test substance.

5.2.1.4 Acute toxicity: other routes

No data available.

5.2.2 Human information

No data available.

5.2.3 Summary and discussion of acute toxicity

The LD50 oral and dermal are higher than 2000 mg/kg bw in rats. No inhalation data are available but respiratory exposure is assumed to be limited for poorly water-soluble dusts.

5.3 Irritation

5.3.1 Skin

Not relevant for this evaluation

5.3.2 Eye

Not relevant for this evaluation

5.3.3 Respiratory tract

No data available.

5.3.4 Summary and discussion of irritation

Not relevant for this evaluation.

5.4 Corrosivity

Not relevant for this evaluation.

5.5 Sensitisation

5.5.1 Skin

Not relevant for this evaluation.

5.5.2 Respiratory system

No data available.

5.5.3 Summary and discussion on sensitisation

Not relevant for this evaluation.

5.6 Repeated dose toxicity

5.6.1 Non-human information

5.6.1.1 Repeated dose toxicity: oral

The following studies were performed:

OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents) on rat (Sprague-Dawley) by gavage resulted in NOAEL 100 mg/kg bw/day.

OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents) on rat (Wistar) feeding study with NOAEL 1000 mg/kg diet (male/female) based on substance (body weight, organ weights). The nominal values recalculated from food consumption (mg/kg diet) are NOAEL 98 mg/kg bw/day (female) and NOAEL 82 mg/kg bw/day (male).

Based on the available data no classification criteria have been met.

5.6.1.2 Repeated dose toxicity: inhalation

No data available.

5.6.1.3 Repeated dose toxicity: dermal

No data available.

5.6.1.4 Repeated dose toxicity: other routes

No data available.

5.6.2 Human information

No data available.

5.6.3 Summary and discussion of repeated dose toxicity

No data are available on dermal or inhalation route.

Subchronic repeated dose toxicity studies revealed reduced body weight and increased weight of some organs in the two highest doses after correction for body weight in last week but no adverse effects which could lead to classification.

As critical value for exposure assessment of long-term systemic effects the NOAEL from subchronic long-term toxicity study 82 mg/kg bw/day was chosen.

5.7 Mutagenicity

5.7.1 Non-human information

No adverse effect was observed according to genetic toxicity in all in vitro and in vivo performed tests. Based on the available data no classification criteria have been met.

5.7.2 Human information

No data available.

5.7.3 Summary and discussion of mutagenicity

No adverse effect was observed according to genetic toxicity in all in vitro and in vivo performed tests. Based on the available data no classification criteria have been met.

5.8 Carcinogenicity

No data available.

5.9 Toxicity for reproduction

5.9.1 Effects on fertility

5.9.1.1 Non-human information

The robust study summary needs to include detailed information on sperm examination: motility, morphology and number (number of homogenisation-resistant testicular spermatid, number of cauda epididymal sperm) as minimum and oestrous cycle evaluation.

An OECD 415 study is available. The records on fertility revealed that oestrous cycle parameter was monitored but not semen analysis.

However, a sub-chronic repeated dose toxicity study did not reveal any adverse effects on reproductive organs or tissues but increased weight of some organs including testes was noted in highest dose after correction for body weight in last week.

The study according to OECD 415 gives information about fertility effects which are associated with maternal toxicity.

It is concluded, that effects observed on the offspring are connected to maternal toxicity. Based on the available data the Czech MSCA does not see a concern for fertility and does not see the need to request further information.

5.9.1.2 Human information

No data available.

5.9.2 Developmental toxicity

5.9.2.1 Non-human information

The provided Prenatal developmental toxicity study (OECD 414) was performed in accordance to older study guideline. The females were administered the test substance from 6th day to 15th day of pregnancy. In accordance to the current study guideline the females should be administered the tested substance from 5th day to 19th day of pregnancy.

Potential malformation of organs developing in the last part of pregnancy (e.g. sex organs and brain) may not be detected if the study is performed according to the older guideline for the teratology study.

For this reason, more detailed information on malformations at dose 300 mg/kg bw/day was required to assess the relevance of this effect. Reproductive parameters of females were not influenced, no skeletal abnormalities were observed in foetuses or effect on soft tissues and for all effects was noted that they are within laboratory historical controls.

5.9.2.2 Human information

No data available.

5.9.3 Summary and discussion of reproductive toxicity

Based on the available information the Czech MSCA concludes that there is no concern for reproductive toxicity. In addition, the substance as such is used in closed systems when mixture is formulated and subsequently is used as mixture with low substance concentration in up to 1% in coating device under containment. The substance is within coating bound on matrix by polymer layer in consumer products.

5.10 Endocrine disrupting properties

No data available.

5.11 Other effects

No data available.

5.12 Combined effects

No data available.

5.13 Derivation of DNEL(s) / DMEL(s)

It is concluded that DNEL(s) in exposure assessment provided by lead registrant dossier are suitable for risk assessment.

5.13.1 Overview of typical dose descriptors for all endpoints

Overall the effects from studies have not met classification criteria. As critical value for exposure assessment of long-term systemic effects the NOAEL from subchronic repeated dose toxicity study 82 mg/kg bw/day was chosen.

5.13.2 Quantitative descriptor for critical health effects

NOAEL 82 mg/kg bw/day (Repeated dose toxicity)

5.14 Conclusions of the human health hazard assessment and related classification and labelling

Overall the result effects observed in studies have not met classification criteria.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO CHEMICAL PROPERTIES

6.1. Explosivity

Not relevant for this evaluation

6.2. Flammability

Not relevant for this evaluation

6.3. Oxidising potential

Not relevant for this evaluation

7 ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

7.1.1 Toxicity data

7.1.1.1 Fish

7.1.1.1.1 Short-term toxicity to fish

No toxic effects occurred up to substance water solubility in a GLP study according to OECD Guideline 203 (Fish, Acute Toxicity Test, *Danio rerio*) with DMSO as a solvent.

LC50 (96 h): > 0.1 mg/L

7.1.1.1.2 Long-term toxicity to fish

The L(E)C50 values from acute tests on all three trophic levels for fish, algae and daphnids exceeded the range of substance water solubility (0.027 mg/L) in all cases. The NOEC on daphnids in long term study as well. Thus, the substance had been considered by most of registrants as not acutely harmful to aquatic organisms in the range of water solubility.

However, measured concentration in the end of the exposure period indicates that the substance was not detected in provided long term test on daphnids.

A valid long-term test on fish was not available. Chronic toxicity can be proven only on early stages of fish and there were only data for the adult fish in registrant´s dossier.

The initially provided test OECD 204 prolonged aquatic toxicity test on fish is not considered as chronic toxicity test because of the sensitive life stages are not exposed and it is only prolonged acute study with fish mortality as the major endpoint to be examined.

Based on those data it could not be determined from available data if fish is likely to be less sensitive than *Daphnia*, therefore there was the need to require an alternative test.

The long term study on fish FELS (Fish, Early Life Stage) was requested in draft decision to clarify long-term effects in environment.

The provided long-term toxicity FELS test was based on the value of water solubility from source with specification of the test method and conditions. This value is considered as reliable value for substance evaluation as well.

The submitted FELS test demonstrates the long-term effects on the early stages of fish. Based on information from this test the initial concern was confirmed. The derived NOEC was lower than water solubility 0.0048 mg/L and used for deriving of PNEC (more in confidential Annex)

The classification criteria have been met and it leads to Aquatic Chronic 1 classification.

7.1.1.2 Aquatic invertebrates

7.1.1.2.1 Short-term toxicity to aquatic invertebrates

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test, *Daphnia magna*, freshwater);

EC50 (24 h): > 0.1 mg/L based on mobility

The L(E)C50 value from an acute test on daphnids exceeded the range of substance water solubility.

7.1.1.2.2 Long-term toxicity to aquatic invertebrates

OECD Guideline 211 (Daphnia magna Reproduction Test, *Daphnia magna*, freshwater, semi-static) extended according to Draft proposal for an update of OECD Guideline 202, Part II (1991).

NOEC of 0.036 mg/L was above the substance water solubility 0.027 mg/L, however the measured concentration in the end of the exposure period indicated a sudden loss of concentration and the substance was not detected.

Therefore the long term study on fish was required in Draft Decision to clarify long-term effects in environment as was described above in Section 7.1.1.1.2.

7.1.1.3 Algae and aquatic plants

Tests provided in aggregated dossiers were performed according to OECD Guideline 201 (Alga, Growth Inhibition Test, *Desmodesmus subspicatus*, freshwater, static). Tests result in NOEC (72 h) based on growth rate and determined as measured arithmetic mean: 90 µg/L.

The later test was performed in 2005 with OECD recommendations for difficult substances included the analytical verification using HPLC-UV when the initial measured concentration was 41 µg/L and the final concentration was 22.6 µg/L and the geometric mean is 30.4 µg/ L which is close to the substance solubility but still no toxic effects occur in the range of water solubility.

7.1.1.4 Sediment organisms

No data available.

7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1 PNEC water

The submitted FELS test demonstrated the long-term effects on the early stages of fish, NOEC lower than water solubility was derived so finally PNECwater is based on these test results.

PNEC aqua (freshwater) = 0.032 µg/L

7.1.2.2 PNEC sediment

PNEC for sediment was derived using the equilibrium partitioning method.

PNECsediment (freshwater) = 0.062 mg/kg sediment dw.

7.2 Terrestrial compartment

7.2.1 Toxicity test results

7.2.1.1 Toxicity to soil macro organisms

OECD Guideline 207 (Earthworm, Acute Toxicity Test); *Eisenia fetida*

NOEC (14 d): 1000 mg/kg artificial soil (nominal, dry weight)

Conclusions related to the concern (related to waste disposal on landfill of paper products containing the substance).

Earthworms are preferred due to overall uptake by surface contact, porewater and soil ingestion as well and as no effects in chronic toxicity occurred at the limit of water solubility another studies were not provided.

The test substance is poorly soluble in water, considered as very persistent and adsorbs to the solid particles of soil based on determined Koc. Furthermore, for a substance not acutely toxic in the range of water solubility and especially for poorly soluble substances it is not possible to derive a robust PNEC for the purposes of a soil screening assessment from acute aquatic toxicity testing as it is not a reliable indicator for potential effects on soil organism due to the low exposures in the test.

Although the long-term effects in aquatic organisms up to the substance solubility limit were detected a long-term test should be performed when substance is very persistent in soil and highly adsorptive of log Kow/Koc >5. The substance values used for assessment are experimental value Koc 4.29 at 30°C according to C19 using HPLC analysis (other value log Koc 5.26, HPLC analysis) and log Kow 5 which both are close to limit but not considered as critical.

7.2.1.2 Toxicity to terrestrial plants

No data available.

7.2.1.3 Toxicity to soil micro-organisms

No data available.

7.2.1.4 Toxicity to other terrestrial organisms

No data available.

7.2.2 Calculation of Predicted No Effect Concentration (PNEC soil)

PNEC soil was determined based on result of the acute test according to OECD 207 on *Eisenia fetida*.

7.3 Atmospheric compartment

The test substance is not listed in Annex I of Regulation (EC) 2037/2000.

7.4 Endocrine disrupting properties

No data available.

7.5 Microbiological activity in sewage treatment systems

7.5.1 Toxicity to aquatic micro-organisms

The IC50 of the test compound on activated sludge was determined to be 202 mg/L (nominal concentration, 30 min).

7.5.1.1 Other aquatic organisms

No data available.

7.5.2 PNEC for sewage treatment plant

Results from testing above the solubility limit are unrealistic due to removing undissolved substance in previous steps in STP, which does not influence activated sludge. But still these values can be used to derive a PNECstp owing to the fact that undissolved substance in microbial tests is found to be less confounding and it is a conservative estimate.

7.6 Non compartment specific effects relevant for the food chain (secondary poisoning)

The available information on possible bioaccumulation potential has been studied and subsequently secondary poisoning is not relevant for exposure assessment.

7.6.1 Toxicity to birds

No data available.

7.6.2 Toxicity to mammals

No data available.

7.6.3 Calculation of PNECoral (secondary poisoning)

Not relevant for exposure assessment (see 7.6 Secondary poisoning)

7.7 Conclusion on the environmental hazard assessment and on classification and labelling

Harmonised Classification in Annex VI of the CLP Regulation

Index No: 603-128-00-0
Chemical name: 2-(phenylmethoxy)naphthalene
EC No: 405-490-3
CAS No: 613-62-7
Classification: Aquatic Chronic 4
Hazard statement: H413

Conclusion on the environmental hazard assessment:

Based on existing data and the long term study on fish early stages provided under substance evaluation, the following is concluded:

The L(E)C50 values from an acute tests on all three trophic levels for fish, algae and daphnids exceeded the range of substance water solubility (0.027 mg/L) in all cases. The NOEC on daphnids in long term study as well.

The IC50 of the test compound on activated sludge was determined to be 202 mg/L (nominal concentration, 30 min).

However, measured concentration at the end of the exposure period indicates that the substance is not detected in provided long term test on daphnids.

The provided long-term toxicity FELS test was based on the value of water solubility from source with specification of the test method and conditions. This value is considered as reliable value for substance evaluation as well.

The submitted FELS test demonstrates the long-term effects on the early stages of fish, then based on information from this test the initial concern was confirmed. The NOEC was derived lower than water solubility and used for deriving of PNECwater.

Self-classification based on results from long term Fish, Early-Life Stage (FELS) Toxicity Test OECD Test Guideline 210:

Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects, M-factor 10

Consequently it was possible make a conclusion on the toxicity of substance and to examine the extent of exposure.

8 PBT and vPvB ASSESSMENT

8.1 Assessment of PBT/vPvB properties – Comparison with the criteria of Annex XIII

8.1.1 Persistence assessment

Evidence of P or vP properties

All tests provided by registrants result in conclusion no or poorly biodegradation the evaluated substance. Determined Koc value indicates that the substance will be adsorbed to the soil and sludge and is unlikely to leach due to the low water solubility and high log Kow.

In view of the findings referred to bioconcentration evaluated substance, which enabled conclusion on bioaccumulation, and also due to provided exposure assessment and practically no biodegradation, the simulation studies in surface water and sediments are not required anymore.

The substance is considered as persistent or potentially very persistent in the environment.

8.1.2 Bioaccumulation assessment

Screening criteria

Criteria based on Annex XIII of REACH

Not B/vB based on BCF < 2000 L/kg taking into account measured and estimated values.

There could not be unequivocally stated not B although the determined Kow from previous SNIF was 4.46 (20°C), but from updated SNIF is determined 5.0 (21°C).

Based on these measured Kow values provided and QSAR values log Kow 4.96 (EPI SUITE) and 4.74, respectively (TOPKAT 6.2; 95% confidence limits from 4.34 to 5.14) the criterion B thus could be fulfilled.

On the contrary the QSAR BCF value (EPI SUITE/ BCF v.3.01) considered is 870 thus not fulfilling the B criterion.

The data for evaluation from existing robust study summaries the from initial registration dossiers on OECD Guideline 305E (Bioconcentration: Flow-through Fish Test, 1990) and other information related to B/vB criterion was not sufficient to draw unequivocal conclusion based on information.

Upon request in the draft decision, a test on bioconcentration was provided by the lead registrant, which contained information in a sufficient detail. This enabled the confirmation of its validity and consequently a conclusion on the bioaccumulation status of substance.

Based on review of the full study report for the OECD Guideline 305 study and taking into account current approach from adopted guidance on bioconcentration the substance is not considered as B.

Conclusion on B / vB properties: not B/vB

8.1.3 Toxicity assessment

The NOEC provided previously in registrant´s dossiers was determined from test which is not adequate to information requirements as chronic test for fish. The chronic test for daphnids is not sufficiently described (loss of substance to concentration under limit of detection). Therefore it was necessary to prove long-term toxicity in aquatic compartment under conditions for poorly soluble substance.

The provided test FELS (Fish, Early Life Stage) according to OECD Guideline 210 is part of lead registrant dossier which has been submitted after Draft decision. Based on test data the substance fulfils the T criterion.

Conclusion on T properties: T

8.1.4 Summary and overall conclusions on PBT and vPvB Properties

Based on available data the substance is considered as P/vP. The long term study on toxicity fulfils the T criterion according to Annex XIII of REACH.

Detailed examination of the available study on bioconcentration together with the available low QSAR estimation did not prove potential for bioaccumulation. Consequently the substance is not considered as PBT/vPvB.

9 EXPOSURE ASSESSMENT

The exposure assessment has been performed by registrants taking into account the results in the lead registrant dossier supplemented by studies required in draft decision. Evaluating MSCA performed revision of this exposure assessment considering DNELs and PNECs and aggregated tonnage as well. This assessment is a part of Confidential annex.

Based on the available information, measures at industrial sites effectively preventing exposure of aquatic compartment were implemented since the substance is self-classified by registrants as Aquatic Chronic 1.

Direct exposure of soil or sediment is not expected to occur and sludge appears not to be spread on soil but it is incinerated so indirect exposure does not exist as well.

10 REFERENCES

Study reports by test laboratories and industry:

Stated in Confidential Annex

Study reports by regulatory bodies:

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Study reports by international organisations:

United Nations (2007), Guidance on hazards to the aquatic environments, Annex 9, Appendix IV, p. 529, http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev02/English/13e_annex9.pdf

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ECETOC (1995) Technical report no 67, The role of Bioaccumulation in Environmental Risk Assessment: The Aquatic Environment and Related Food Webs, ISSN-0773-8072-67

Masanori Terasaki, Hitoshi Fukazawa, Yukinori Tani, Masakazu Makino (2007), "Organic pollutants in paper-recycling process water discharge areas: First detection and emission in aquatic environment", Environ Pollut. 2008 Jan 151(1):53-9. Epub 2007 May 23

Gehring, M., Tennhardt, L., Vogel, D., Weltin, D., Bilitewski, B. (2004): Bisphenol A Contamination of Wastepaper, Cellulose and Recycled Paper Products. In: Brebbia, C. A., Kungulos, S., Popov, V., Itoh, H. (eds.): Waste Management and the Environment II. WIT Transactions on Ecology and the Environment, vol. 78, Southampton, Boston: WIT Press, 294 – 300.

Sijm, D., Part, P., Opperhuizen, A., (1993), "The influence of temperature on the uptake rate constants of hydrophobic compounds determined by the isolated perfused gills of rainbow trout (Oncorhynchus mykiss).", Aquat. Toxicol. 25, 1-14.

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ECHA information and databases:

ECHA Registered substances disseminations site, IUCLID dossier, CAS No 613-62-7, Source: European Chemicals Agency, http://echa.europa.eu/web/guest/legal-notice

Guidance issued by OECD related to aquatic toxicity and bioconcentration:

OECD Test Guideline 305 Bioaccumulation in fish: Aqueous and Dietary exposure, Adopted 2 October 2012

OECD Test Guideline 305 Bioconcentration: Flow-through fish test Adopted 14 June 1996

OECD Test Guideline 210 Fish, Early-Life Stage (FELS) Toxicity Test (1992b)

OECD 23 Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures

Other information and databases:

STN International, Literature search, 2012 September 17

REAXYS, 2012 April 27

QSAR Toolbox 2.3.0.1132, 2012 September 21