Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Benzenamine, reaction products with aniline hydrochloride and nitrobenzene

EC No 309-912-6

CAS No 101357-15-7

Evaluating Member State(s): Germany

Dated: July 2020

Evaluating Member State Competent Authority

BAuA
Federal Institute for Occupational Safety and Health
Division 5 - Federal Office for Chemicals
Friedrich-Henkel-Weg 1-25
D-44149 Dortmund, Germany

Year of evaluation in CoRAP: 2019

Member State concluded the evaluation without any further need to ask more information from the registrants under Article 46(1) decision.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

Benzenamine, reaction products with aniline hydrochloride and nitrobenzene (EC No 309-912-6, CAS No 101357-15-7) was originally selected for substance evaluation in order to clarify concerns related to suspected PBT/vPvB properties. During the evaluation, no further concerns were identified.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

A dossier evaluation decision for the substance has been issued by ECHA on 3 May 2016.[2] The decision requested information on its name, manufacturing process, composition as well as in vitro mutagenicity data, a 90-d sub-chronic toxicity study (OECD 408), a long-term toxicity test on fish (OECD 210) and a simulation test on the substance's ultimate degradation in surface water according to OECD 309 and identification of the degradation products. The information was to be provided until 10 November 2017. As of March 2020, the required information on the substance's degradation behaviour is still outstanding.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

Table 1

CONCLUSION OF SUBSTANCE EVALUATION Conclusions	Tick box
Need for follow-up regulatory action at EU level	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
Currently no need for regulatory risk management follow-up action at EU level; Outcome of compliance check need to be awaited first.	X

Due to the delay in the provision of simulation data on biodegradation for the substance the evaluating member state competent authority (eMSCA) considers a final conclusion on the PBT/vPvB concern as not possible at the current time and concludes the substance evaluation according to Article 46(4) without further information requirements as these are currently still ongoing under compliance check. As the member of the joint submission expressed their intention to re-analyse and re-evaluate their substance compositions, information on the substance boundary profile are also still outstanding.

A new substance evaluation by the eMSCA may be warranted once the information becomes available from the previous process.

[2] https://echa.europa.eu/documents/10162/3b15bf28-e051-79df-fbae-147ee34814da

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

Not possible for the time being (see section 3).

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Not possible for the time being (see section 3).

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Indication of a tentative plan is not a formal commitment by the evaluating Member State. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Table 2

FOLLOW-UP		
Follow-up action	**Date for intention**	**Actor**
Subsequent substance evaluation	*tbd*	*DE CA*

The need for a re-opening of the Substance Evaluation process will be determined based on the outcome of the new information generated via the Compliance Check procedure.

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

Benzenamine, reaction products with aniline hydrochloride and nitrobenzene (EC No 309-912-6, CAS No 101357-15-7) was originally selected for substance evaluation in order to clarify concerns related to suspected PBT/vPvB properties. During the evaluation, no further concerns were identified.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
PBT/vPvB	Further information necessary.
Persistency	Further information on the persistency behaviour of the substance is currently being generated under compliance check. There is a high likelihood that the substance or a portion of its constituents is persistent or very persistent.
Bioaccumulation	A series of constituents of the substance fulfil the Bioaccumulation (B) criterion on a screening level. Further information on bioaccumulation may be necessary in the future to clarify whether the substance or a portion of its constituents fulfils the B/vB criterion.
Toxicity	While available data on the substance itself does not point towards fulfilment of the Toxicity (T) criterion, it cannot be excluded that some of its constituents may fulfil the T criterion. In case constituents of the substance are identified as fulfilling the P and B criterion (without being vPvB), information on their toxicity may be necessary.

7.2. Procedure

A PBT/vPvB assessment was conducted based on the available data from the registration dossier and information provided by the registrants. QSAR calculations conducted by the eMSCA were used as supporting information.

7.3. Identity of the substance

Table 4

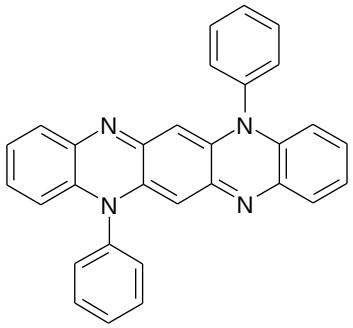
SUBSTANCE IDENTITY	
Public name:	Benzenamine, reaction products with aniline hydrochloride and nitrobenzene
EC number:	309-912-6
CAS number:	101357-15-7

Index number in Annex VI of the CLP Regulation:	Not assigned
Molecular formula:	$C_mH_nN_oO_p$
Molecular weight range:	Cannot be assigned
Synonyms:	*Nigrosin, Nigrosine, CI Solvent Black 7*

Type of substance UVCB

Structural formula:

In the registration it is stated that "the substance is a UVCB substance having a varying number of condensation products of aniline hydrochloride and nitrobenzene. The given constituents should therefore be understood as examples of a isomer present in the substance. The substitution pattern however could be different." One exemplary constituent is:



7.4. Physico-chemical properties

Table 5

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	Black solid powder
Vapour pressure	1.132×10^{-10} Pa at 25°C, according to EU method A.4
Water solubility	<0.1 mg/L at 20°C, according to EU method A.6
Partition coefficient n-octanol/water (Log Kow)	0.518-6.5 at 30°C, pH approx. 9, according to EU method A.8
Flammability	idem
Explosive properties	idem
Oxidising properties	idem
Granulometry	<100 µm: 15.6% <10 µm: 0.741% <5.5 µm: 0.05% According to OECD guideline 110, registrants confirmed that the substance is not a nanomaterial

Stability in organic solvents and identity of relevant degradation products	Waiving according to column 2 of annex IX
Dissociation constant	Due to the poor water solubility a study according to OECD guideline method 112 could have been conducted. Estimated values: ca. -2.52 - ca. -1.4, estimate for when R = aniline. Temperature not reported. ca. 6.19 - ca. 6.57, Estimate for when R = H. Temperature not reported.

7.5. Manufacture and uses

7.5.1. Quantities

Table 6

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐ 10 – 100 t	☐ 100 – 1000 t	☒ 1000- 10,000 t	☐ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

Table 7

USES	Use(s)
Uses as intermediate	Thermoplastic additive for polymers
Formulation	Formulation of mixtures, plastisols, solid matrices, masterbatches /compounds
Uses at industrial sites	Dye for plastic products, inks, toners, paints, papers, textiles
Uses by professional workers	Textile dyes & impregnating products, Toner cartridges
Consumer Uses	Toner cartridges, permanent markers, stamp ink and ink-ribbons
Article service life	Leather, textiles, paper articles, plastic articles,

The substance is used as a dye in plastics, inks, toners, textiles & leather.

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

There is no harmonised classification of the substance.

7.6.2. Self-classification

- In the registration(s):
  Self-heat. 2 H252
- The following hazard classes are in addition notified among the aggregated self-classifications in the C&L Inventory:

Table 8

SELF-CLASSIFICATION			
Hazard Class and Category Code(s)	**Hazard statement code(s)**	**Hazard Class and Category Code(s)**	**Hazard statement code(s)**
Not classified		STOT RE 2	H373 (kidney)
Acute Tox. 4	H302	Aquatic Chronic 2	H411
Acute Tox. 4	H312	STOT RE 2	H373 (skin, lungs) (Oral)
Skin Sens. 1	H317	STOT RE 2	H373 (Hematological s...)
Acute Tox. 4	H332	STOT RE 2	H373 (Respiratory sys...)
Carc. 2	H351	Aquatic Chronic 4	H413
Repr. 2	H361	STOT RE 2	H373 (blood system) (Oral)
STOT SE 1	H370 (blood, heart, ...)	Aquatic Chronic 3	H412
STOT RE 1	H372 (blood, nerve, r...)		

7.7. Environmental fate properties

Benzenamine, reaction products with aniline hydrochloride and nitrobenzene is a UVCB substance. Its exact composition is both unknown and variable. There is still some uncertainty left which constituents or fractions of constituents are present in relevant amounts. According to the ECHA guidance, the PBT/vPvB assessment must take into account the PBT/vPvB properties of relevant constituents.[3] Recommendations for PBT/vPvB assessment of UVCB substances are given in this guidance.[4] As a first step, the substance composition should be profiled for PBT/vPvB assessment.[5] In this context, it may be necessary to generate refined information on the substance composition. If feasible, the "known constituents approach" as described in the guidance[6] could be applied.

[3] ECHA 2017. Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.11: PBT/vPvB assessment. Version 3.0, p. 24. https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f (accessed 17 October 2019)
[4] Ibid., p. 106-116. https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f (accessed 17 October 2019)
[5] Ibid., p. 106. https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f (accessed 17 October 2019)
[6] Ibid., p. 109-110. https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f (accessed 17 October 2019)

Constituents relevant for PBT/vPvB assessment

The proposed composition varies between the different registrations. Based on the available information, it is not fully clear whether this variation originates from the different manufacturing conditions (which are confidential) or from the different methods applied for identification.

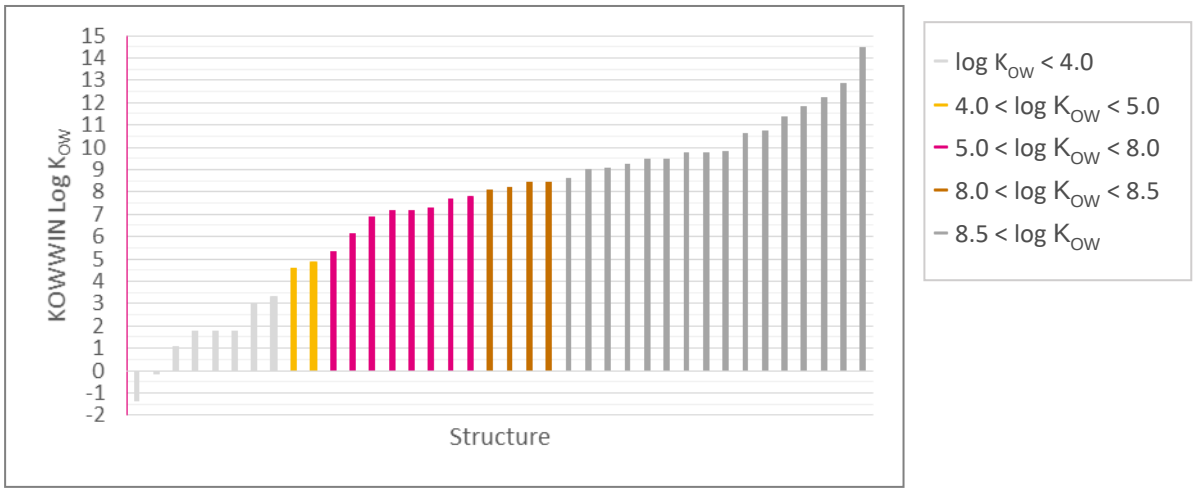
In summary, 38 possible constituents were proposed by the different registrants (ECHA 2019; unpublished study report 2017).

There is still uncertainty whether all these constituents are present at a concentration above or equal to 0.1 % w/w. In order to identify relevant structures for further assessment, several QSAR calculations were conducted as described below and in the following sections.

Log K_{OW} values were used as a first screening criterion before conducting further QSAR estimations on biodegradation (section 7.7.1.2.1.1.) and bioaccumulation (section 7.7.3.1.). The choice of worst-case structures is described in section 7.7.4.

KOWWIN[7] was applied to estimate log K_{OW} values for the above mentioned structures. There are 8 structures with a log K_{OW} < 4.0, for example water, iron dichloride, nitrobenzene or diphenylamine. These are not considered as screening B/vB and have not been evaluated further.

Figure: Estimated log K_{OW} values for 38 proposed constituents.



Log K_{OW} values > 4.5 were estimated for the remaining structures with log K_{OW} values of 16 structures being larger than 8.5 and hence highly hydrophobic. Testing is very challenging for these substances and may even not be technically feasible.

Therefore, the 14 structures with log K_{OW} values ranging from 4.5 to 8.5 were considered as most relevant for further QSAR calculations. These structures are in the molecular weight range of KOWWIN.

7.7.1. Degradation

7.7.1.1. Abiotic Degradation

7.7.1.1.1. Hydrolysis

No information available.

7.7.1.1.2. Phototransformation/photolysis

No information available.

[7] 2010 U.S. Environmental Protection Agency. KOWWIN v1.68.

7.7.1.2. Biodegradation

7.7.1.2.1. Biodegradation in water

7.7.1.2.1.1. Estimated data

A QSAR screening was conducted for the 14 constituents with 4.5 ≤ log K_{OW} ≤ 8.5. Both BIOWIN[8] and CATALOGIC[9] biodegradation models were applied. CATALOGIC, BIOWIN 1, 2, 5 and 6 models use quantitative scores to predict the results of ready biodegradability tests. BIOWIN 3 and 4 use scores to predict ultimate and primary biodegradation, respectively. No clear trend was observed for these scores. However, the three substances with the highest log K_{OW} values (8.21, 8.48 and 8.48) had consistently low biodegradability scores in all models.

All structures are predicted as not readily biodegradable by the CATALOGIC models. 13 out of 14 structures fulfil the BIOWIN related P/vP screening criterion as descrcibed in the PBT guidance (ECHA 2017).[10] The structure not fulfilling the BIOWIN based screening criterion is still predicted not readily biodegradable by some BIOWIN models and all CATALOGIC models. Hence, while this structure may not represent the worst case for persistence, it is potentially not readily biodegradable.

For some structures, CATALOGIC indicated primary degradation and in some of these cases, the predicted metabolites would be potential PBT/vPvB substances as well. A summary table is presented in the confidential annex and more details are given in the attached Excel file. It should be noted that all structures are outside the structural domain of all CATALOGIC models, i.e. there are no similar compounds in the training set. A comparable check for EPISUITE is not conducted automatically. As the QSAR models are applied for screening only, no detailed assessment of applicability domain was conducted. All substances are in the molecular weight range of the BIOWIN models and in the parameter domain of the CATALOGIC models.

7.7.1.2.1.2. Screening tests

Table 9

SUMMARY OF SCREENING TEST RESULTS			
Test method	**Results**	**Reliability**	**Reference**
OECD Guideline 301C	After 28 days: BOD: 4%		(ECHA 2019)

A test on ready biodegradability according to OECD 301C was conducted on the whole substance. Under test conditions, no biodegradation was observed. This result is in agreement with the QSAR estimations.

[8] 2010 U.S. Environmental Protection Agency. BIOWIN v4.10.
[9] OASIS CATALOGIC v.5.13.1.156. Applied models:
- CATALOGIC Kinetic 301B v.02.09
- CATALOGIC Kinetic 301F v.13.16
- CATABOL 301B v.02.07
- CATABOL 301C v.02.08
- CATALOGIC 301C v.11.15

[10] Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time): Does not biodegrade fast (probability < 0.5)* and ultimate biodegradation timeframe prediction: ≥ months (value < 2.25 (to 2.75)**). Or Biowin 6 (MITI non-linear model prediction) and Biowin 3 (ultimate biodegradation time): Does not biodegrade fast (probability < 0.5)* and ultimate biodegradation timeframe prediction: ≥ months (value < 2.25 (to 2.75)**). ECHA 2017, p. 49.

7.7.1.2.1.3. Simulation tests (water and sediments)

Table 10

SUMMARY OF SCREENING TEST RESULTS			
Test method	**Results**	**Reliability**	**Reference**
OECD Guideline 309	Test still ongoing		

There are no respective simulation studies on the substance. However, a simulation test on biodegradation in surface water according to OECD 309 is currently ongoing following a request in a dossier evaluation decision (see section 2 in part A).

7.7.1.2.1.4. Summary and discussion of biodegradation in water and sediment

No biodegradation was observed in an OECD 301C test on the whole substance. Therefore, at least the major constituents can be considered to fulfil the P/vP screening criterion. This result is in accordance with the QSAR results.

7.7.1.2.2. Biodegradation in soil

No relevant information available.

7.7.1.3. Summary and discussion on degradation

Abiotic degradation is not expected. No biodegradation was observed in an OECD 301C test on the whole substance. Therefore, at least the major constituents can be considered to fulfil the P/vP screening criterion. This result is in accordance with the QSAR results.

7.7.2. Environmental distribution

7.7.2.1. Adsorption/desorption

Testing was conducted on the whole substance using the HPLC estimation method. The observed log K_{OC} values range from 0.842 to greater than 5.63; about 61.4 % of the test material have a log K_{OC} greater than 5.63 (ECHA 2019).

7.7.2.2. Volatilisation

Not assessed.

7.7.3. Bioaccumulation

7.7.3.1. Aquatic bioaccumulation

A bioaccumulation study was conducted on the registered substance in accordance with OECD 305C. The substance has multiple constituents and three different peaks were detected in an HPLC-GPC analysis (ECHA 2019). A difference was observed in the bioaccumulation level of these peaks and hence, attempts were made to calculate BCF values specific for these HPLC peaks with values ranging up to 1850 (ECHA 2019). However, there was no further refinement of the respective constituents. An attempt to identify structures from the worst case peak via gas chromatography-mass spectrometry was made, but did not succeed (ECHA 2019).

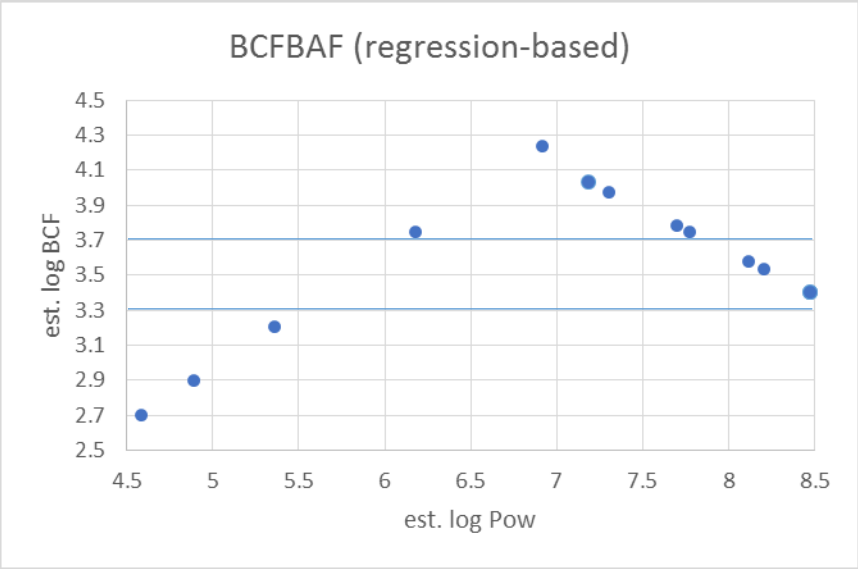
Further points from the full study report (Testing Laboratory 1, 1997) are discussed in the confidential annex.

Table 11

BIOCONCENTRATION FACTORS (BCF)						
Organism	**Exposure [mg/L]**	**Exposure [weeks]**	**BCF whole body [l/kg]**	**Lipid content [%]**	**Rel.**	**Reference**
Cyprinus carpio	0.1	8	7.9 - 41	3.8	3	(Testing Laboratory 1, 1997; ECHA 2019)
	0.01	8	25 - 164			

The regression based BCFBAF model[11] was used to screen 14 potential constituents with log K_{OW} values from 4.5 to 8.5. A table with results is given in the confidential annex.

Figure: Estimated log BCF vs. log K_{OW} for screened constituents



These results indicate that

- BCF is > 5000 for log K_{OW} values from 6.18 to 7.78,
- BCF is > 2000 but < 5000 for log K_{OW} values from 8.12 to 8.48 and
- BCF is < 2000 for log K_{OW} values ≤ 5.36.

The eMSCA notes that these QSAR results are subject to considerable uncertainty[12] and therefore are used for screening purposes only. All 14 structures are considered as screening B/vB as their log K_{OW} values are larger than 4.5.

[11] 2012 U.S. Environmental Protection Agency. BCFBAF v3.01.

[12] In a comparative study, BCFBAF underestimated experimental BCF values:

Müller, Martin & Nendza, Monika. (2011). Comparative analysis of estimated and measured BCF data (OECD 305) – Literature study with a special focus on differential accumulation of (mixtures of) stereoisomers. 10.13140/2.1.2922.4963.

7.7.3.2. Terrestrial bioaccumulation

Not assessed.

7.7.3.3. Summary and discussion on bioaccumulation

Some constituents have log K_{OW} values > 4.5 and are therefore screening B/vB. The available BCF study was conducted for the whole substance and does not allow to conclude on bioaccumulation of the relevant constituents.

7.7.4. Identification of potential worst case constituents

QSAR calculations were used to identify potential worst case constituents.

1st step: log K_{OW} Screening

In a first step, log K_{OW} was estimated to identify substances that fulfil the bioaccumulation screening criterion (log K_{OW} > 4.5) and can be tested with current bioaccumulation test methods (log K_{OW} ≤ 8.5). More details on the log K_{OW} screening are given in section 7.7 above.

As a result, 14 structures with log K_{OW} values ranging from 4.5 to 8.5 were considered as most relevant for further QSAR calculations.

2nd step: Biodegradation Worst Case Screening

BIOWIN and CATALOGIC biodegradation models were applied for the 14 constituents identified in step 1. The results are discussed in section 7.7.1.2.1.1. above. In the absence of clear quantitative trends across all models, the following criteria were applied to identify worst case structures:

1) The substance is not predicted to biodegrade fast neither in any of the BIOWIN aerobic biodegradability models (value < 0.5, BIOWIN 1,2,5,6) nor in any of the CATALOGIC models (value < 0.6, all applied CATALOGIC models[13]).

2) The ultimate biodegradation timeframe prediction is ≥ months (value < 2.25, BIOWIN 3).

3) The primary biodegradation timeframe prediction is ≥ weeks to months (value < 2.75, BIOWIN 4).

4) The available CATALOGIC models do not indicate a primary degradation half life < 1 month.

Applying these criteria, eight constituents were identified as persistence worst case. Based on criteria 1) and 2), there is no indication of fast biodegradation and the persistence screening criterion as described in the relevant guidance[14] is fulfilled. Based on criteria 3) and 4), no fast primary degradation is expected.

[13] OASIS CATALOGIC v.5.13.1.156. Applied models:
- CATALOGIC Kinetic 301B v.02.09
- CATALOGIC Kinetic 301F v.13.16
- CATABOL 301B v.02.07
- CATABOL 301C v.02.08
- CATALOGIC 301C v.11.15

[14] Table R.11-4: Screening information for P and vP. In: ECHA 2017. Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.11: PBT/vPvB assessment. Version 3.0, p. 49. https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f (accessed 08 October 2019):

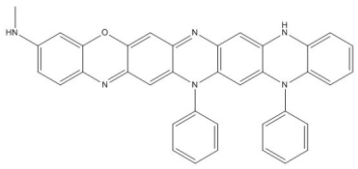
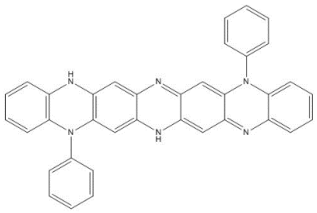
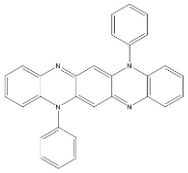
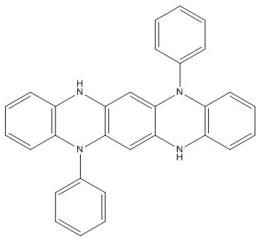
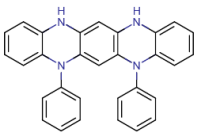
3rd step: Bioaccumulation Worst Case Screening

The regression based BCFBAF model was applied for the 14 constituents identified in step 1. A description of the results is given in section 7.7.3.1. Seven constituents with predicted BCF values > 5000 were considered as bioaccumulation worst cases.

4th step: Combination of Persistence and Bioaccumulation Worst Case Screening

Five structures are both persistence and bioaccumulation worst cases (see table 12). These are considered potential worst case constituents.

Table 12

POTENTIAL WORST CASE CONSTITUENTS			
Name	**Structure**	**Molecular Weight**	**Estimated log KOW**
1,3-Diphenyl-8-methylamino-[1,3,5,12,14-pentaaza]-10-oxo-[1,3,5,10-tetrahydro]-heptacene		570	7.78
1,10-Diphenyl-[1,3,5,10,12,14-hexaaza]-[1,3,10,14-tetrahydro]-heptacene		540	7.7
5,12-diphenyl-5,12-di-hydroquinoxalino¬[2,3 b]¬phenazine		436.5	7.31
7,14-diphenyl-12,12a-dihydroquinoxalino[2,3-b]phenazine, 5,12-diphenyl-5,7,12,14-tetrahydro-5,7,12,14-tetraazapentacene		438.5	7.19
5,7-diphenyl-5,7,12,14-tetrahydroquinoxalino[2,3-b]phenazine, 5,7-diphenyl-5,7,12,14-tetrahydro-5,7,12,14-tetraazapentacene		438.5	7.19

7.8. Environmental hazard assessment

7.8.1. Aquatic compartment (including sediment)

7.8.1.1. Fish

Table 13

SUMMARY OF SHORT-TERM EFFECTS TO FISH			
Test method	**Results**	**Reliability**	**Reference**
OECD 203	Oncorhynchus mykiss Limit test EC50(96h) > 2mg/L [nom.]	1	(ECHA 2019)

Table 14

SUMMARY OF LONG-TERM EFFECTS TO FISH			
Test method	**Results**	**Reliability**	**Reference**
OECD 210	Pimephales promelas FELS NOEC (32d): 0.072 mg/L [nom.]	1	(ECHA 2019)

7.8.1.2. Aquatic invertebrates

Table 15

SUMMARY OF SHORT-TERM EFFECTS TO AQUATIC INVERTEBRATES			
Test method	**Results**	**Reliability**	**Reference**
OECD 202	Daphnia magna, static, EC50 (48h) > 0.071 mg/L [meas.]	1	(ECHA 2019)

Table 16

SUMMARY OF LONG-TERM EFFECTS TO AQUATIC INVERTEBRATES			
Test method	**Results**	**Reliability**	**Reference**
OECD 211	Daphnia magna, semi-static NOEC (21d) ≥ 0.021mg/L (meas.) based on immobilization	1	Priestly SL and Mullee DM 2009

7.8.1.3. Algae and aquatic plants

Table 17

SUMMARY OF EFFECTS TO ALGAE AND AQUATIC PLANTS			
Test method	**Results**	**Reliability**	**Reference**
OECD 201	Desmodesmus subspicatus; EC50(72h)>0.028 mg/L (meas.) NOEC(72h)=0,028 mg/L (meas.) based on growth rate	1	

7.8.2. Terrestrial compartment

7.8.3. Microbiological activity in sewage treatment systems

Table 18

EFFECT ON MICROORGANISMS			
Test method	**Results**	**Reliability**	**Reference**
OECD 209	EC50 (3 h): > 1000 mg/L test mat. (nominal) based on: respiration rate NOEC (3 h): 1000 mg/L test mat. (nominal) based on: respiration rate		(ECHA 2019)

7.8.4. Summary and discussion on environmental hazard assessment

Tests reported in section 7.8.1 all used the UCVB as a test substance. There were no statistically significant treatment related effects on respective endpoints observed in studies summarized in section 7.8.1 until limit of solubility of the test substance.

In summary, the available information does not indicate that the T criterion is fulfilled. However, a final conclusion on the single constituents is not possible based on test results for the whole substance.

7.9. Human Health hazard assessment

Not assessed as part of the substance evaluation.

7.10. Assessment of endocrine disrupting (ED) properties

Not assessed as part of the substance evaluation.

7.11. PBT and VPVB assessment

7.11.1. Persistence assessment

No biodegradation was observed in an OECD 301C test on the whole substance. Therefore, at least the major constituents fulfil the persistence screening criterion. This result is in accordance with the QSAR results.

7.11.2. Bioaccumulation assessment

The available BCF study was conducted for the whole substance and has several shortcomings. This study does not allow to conclude on bioaccumulation of the relevant constituents. Some constituents have log K_{OW} values > 4.5 and therefore fulfill the screening criterion for bioaccumulation.

7.11.3. Toxicity assessment

In summary, the available information does not indicate that the toxicity criterion is fulfilled. However, a final conclusion on the single constituents is not possible based on test results for the whole substance.

7.11.4. Overall conclusion on PBT and vPvB Properties

There is limited information available on relevance and concentration of the proposed constituents of the substances. However, the PBT/vPvB screening criteria are fulfilled both based on experimental data for the whole substance and based on QSAR results for selected constituents.

Further information on the constituents is required to identify worst case structures / fractions for PBT/vPvB assessment.

7.12. Exposure assessment

Not assessed as part of the substance evaluation.

7.13. Risk characterisation

Not assessed as part of the substance evaluation.

7.14. References

Unpublished study report M 2017. QSAR Estimation of the Bioaccumulation Potential of Components of Nigrosine (EC 309-912-6), 2017.

ECHA 2017. Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.11: PBT/vPvB assessment. Version 3.0. https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f (accessed 16.08.2019)

ECHA 2019. Benzenamine, reaction products with aniline hydrochloride and nitrobenzene. https://echa.europa.eu/de/registration-dossier/-/registered-dossier/13119/1 (last accessed 15.08.2019)

Testing Laboratory 1, 1997. Bioaccumulation Study of Solvent Black-7 in carp (test substance No. K-1215). Translation from English to Japanese.

7.15. Abbreviations

BCF	bioconcentration factor
B/vB	bioaccumulative / very bioaccumulative
BOD	biological oxygen demand
eMSCA	evaluating Member State Competent Authority
FELS	Fish early life stage
GPC	Gel permeation chromatography
HPLC	high performance liquid chromatography
K_{OW}	octanol water partition coefficient
Meas.	measured
NOEC	no observed effect concentration
Nom.	nominal
PBT	persistent, bioaccumulative, toxic
P/vP	persistent / very persistent
QSAR	Quantitative Structure-Activity Relationship
T	toxic
vPvB	very persistent, very bioaccumulative