Committee for Risk Assessment

RAC

Opinion

proposing harmonised classification and labelling at Community level of

(Z)-octadec-9-enylamine

ECHA/RAC/CLH-O-0000002197-73-01/F

Adopted

2 December 2011

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OPINION OF THE COMMITTEE FOR RISK ASSESSMENT ON A DOSSIER PROPOSING HARMONISED CLASSIFICATION AND LABELLING AT COMMUNITY LEVEL

In accordance with Article 37(4) of the Regulation (EC) No 1272/2008 (CLP Regulation), the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling of

Substance Name: ***(Z)-octadec-9-enylamine***

EC Number: ***204-015-5***

CAS Number: ***112-90-3***

The proposal was submitted by ***Germany***
and received by RAC on ***19 October 2010.***

The proposed harmonised classification

	CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC (criteria)
Current entry in Annex VI CLP Regulation	-	-
Current proposal for consideration by RAC	Acute Tox 4, H302; Skin Corr 1B, H314; STOT SE 3, H335; STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 M-factor= 10	Xn,C,N; R 22-34-37-48/22-50/53
Resulting harmonised classification (future entry in Annex VI CLP Regulation)	Acute Tox 4, H302; Skin Corr 1B, H314; STOT SE 3, H335; STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 M-factor= 10	Xn,C,N; R 22-34-37-48/22-50/53 N; R50-53: C ≥ 2,5 % N; R51-53: 0,25 % ≤ C < 2,5 % R52-53: 0,025 % ≤ C < 0,25 %

PROCESS FOR ADOPTION OF THE OPINION

Germany has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at ***http://echa.europa.eu/consultations/harmonised_cl/harmon_cl_prev_cons_en.asp*** on ***19 October 2010***. Parties concerned and MSCAs were invited to submit comments and contributions by ***03 December 2010***.

ADOPTION OF THE OPINION OF RAC

Rapporteurs appointed by RAC: ***Céu Nunes and Paola Di Prospero Fanghella***

The opinion takes into account the comments of MSCAs and parties concerned provided in accordance with Article 37(4) of the CLP Regulation.

The RAC opinion on the proposed harmonised classification and labelling has been reached on ***2 December 2011,*** in accordance with Article 37(4) of the CLP Regulation, giving parties concerned the opportunity to comment. Comments received are compiled in Annex 2.

The RAC Opinion was adopted by ***consensus***.

OPINION OF RAC

The RAC adopted the opinion that ***(Z)-octadec-9-enylamine*** should be classified and labelled as follows:

Classification & Labelling in accordance with the CLP Regulation

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	(Z)-octadec-9-enylamine	204-015-5	112-90-3	Acute Tox. 4 Skin Corr. 1B Asp Tox. 1 STOT SE 3 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H314 H304 H335 H373 (gastrointestinal-tract, liver, immune system) H 400 H 410	GHS05 GHS07 GHS08 GHS09 Dgr	H302 H314 H304 H335 H373 (gastrointestinal-tract, liver, immune system) H410		M= 10 (acute) M = 10 (chronic)	None

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	(Z)-octadec-9-enylamine	204-015-5	112-90-3	Xn; R22-48/22-65 C; R34 N; R50/53	C; N R:22-34-48/22-65 50/53 S: (1/2-)23-26-36/37/39-45-60-61-62	C; R34: C ≥ 10% Xi; R36/37/38: 5% ≤ C < 10% N; R50-53: C ≥ 2,5 % N; R51-53: 0,25 % ≤ C < 2,5 % R52-53: 0,025 % ≤ C < 0,25 %	None

Background information

(Z)-octadec-9-enylamine has already been prioritised under the Existing Substance Regulation (ESR) (EEC) No 793/93 and was classified at TC C&L 09/2005 and confirmed at TC C&L 04/2006, but this decision was not included in an ATP to Directive 67/548/EEC. Hence, action on a community-wide basis is required to finalise the harmonised classification and labelling under Regulation (EC) No 1272/2008, and to include the C&L proposal in an ATP of the Regulation.

SCIENTIFIC GROUNDS FOR THE OPINION

It is to point out that a grouping approach was followed in the CLH report for the follow five amines: Coco alkyl amines, Tallow alkyl amines, (Z)-octadec-9-enylamine, amines, Hydorgenate tallow alkyl, Octadecylamine. The five different primary alkyl amines were evaluated together in a 'many-to-many read-across' approach based on similarity in terms of physicho-chemical properties, common functional groups and common metabolic breakdown products. In this context the read-across approach is not to intended based only on one-to-many read-across but was rather derived from a synopsis of the available studies for all the amines in question.

Other Hazard Classes
Acute toxicity

Based on the relevant acute oral study (with an LD50 of 1689 mg/kg bw/ day) (Z)-octadec-9-enylamine, should be classified as Acute Toxicity Class 4 and the hazard phrase H302 should be assigned according to the GHS as adopted by the EU CLP Regulation (Reg. (EC) 1272/2008), and Xn;R22 should be assigned following the criteria of Annex VI to Dir. 67/548/EEC.
Agreement for this proposal was expressed during the public consultation.

Other Hazard Classes
Aspiration Hazard

The primary alkyl amines contain a long linear hydrocarbon moiety significantly influencing their physicochemical properties although for the presence of a nitrogen atom, are not hydrocarbons in the narrow sense. In the CLP Regulation Substances in Category 1 include but are not limited to certain hydrocarbons, turpentine and pine oil.
The kinematic viscosity of ***(Z)-octadec-9-enylamine*** is 6.4 x mm^2/s at 60 °C. This value is below the threshold value of 20,5 mm^2/s (at 40 °C): under this value a substance is classified in Category 1 for Aspiration Hazard R65-H304 according to point 3.10, table 3.10.1 of EU CLP Regulation 1272/2008 and according to DSD (kinematic viscosity for classification < 7 x mm^2/s at 40 °C).
It is to note that, although the kinematic viscosity for both CLP Regulation and DSD, is estimated at 40 °C, it is our opinion that the value calculated at 60 °C is very low and cannot exceed the threshold value for classification even if the measure was made at 40 °C.

The clinical symptoms observed (laboured breathing, rattling noises) in oral acute toxicity studies and the severe lung damage frequently observed in repeated oral toxicity studies, both by gavage and in the diet, could be attributed to the aspiration of test substance as aspiration might occur accidentally during theses procedures. As these findings cannot be attributed with sufficient certainty to substance treatment or to the aspiration of the substance into the lungs they can be considered as supportive data for aspiration hazard.

Repeat dose toxicity
Based on the read across approach proposed for all amines the oral 28-day study on rats on tallow alkyl amines whit a LOAEL of 12,5 mg/kg bw/day is considered as key study.

Leading health effects in this study were delayed mortalities associated with precedent bad general health status and gait abnormalities, erosions of the mucosa of the gastrointestinal tract, accumulation of (material-) loaded histiocytes in the submucosa of the distal parts of the small intestine and in the mesenterial lymph nodes associated with inflammatory granuloma formation, liver toxicity, and indications of immunosuppression occurring at 150 mg/kg bw/d, which is within the critical dose range for STOT RE Cat 2 or R48/22, respectively.
This is supported by findings in the studies on other fatty alkyl amines. Overall, the following effects were regarded as critical for classification:

- Delayed mortalities and erosion of gastrointestinal mucosa at 150 mg/kg bw/d (28-day study, tallow alkyl amines)
- Gait abnormalities at non-lethal, non-irritating concentrations (50 mg/kg bw/d, 28-day study, octadecenylamine)
- Treatment-related reduction in food consumption (≥ 7-8 mg/kg bw/d, subacute study, hydrogenated tallow alkyl amines) resulting in growth depression and anorexia. Effects could be interpreted as non-specific toxicity. However, intestine dysfunction such as malabsorption could also be a possible consequence of morphological damage of the intestine (through intramural substance accumulation and responsive inflammation and hyperplasia of intestinal wall).
- Accumulation of test material in the intestinal wall and in mesenteric lymph nodes (≥ 12 mg/kg bw/d, 28-day study, rat; 15 mg/kg bw/d, tallow alkyl amines; 1-year dog, octadecylamine). The effect is already present at non-irritating dosages. There is no excretion pathway for intracellular material, some redistribution among cells or among organs may be possible through re-phagocytosis or migration of loaden histiocytes. The effect is irreversible.
- Accumulation enteropathy is associated with inflammatory and hyperplastic responses of the intestine: Histiocytic granuloma in the intestinal wall and mesenteric lymph nodes, histiocytic hyperplasia in mesenteric lymph nodes, mucosal hyperplasia in the intestine. Related to the persistence of accumulated material, granuloma formation will also persist during life.
- Disturbance of lipid metabolism (8 mg/kg bw/d, 14-day study, octadecylamine): the significance/relevance of these findings cannot be assessed, but a lack of phospholipids, for example might affect central nervous function or lung function.
- Treatment-related liver toxicity (150 mg/kg bw/d, 28 day study, tallow alkylamines, 50 mg/kg bw/d, 28 day study, octadecenylamine). In addition, histiocytic granuloma formation in the liver is likely to be a secondary effect caused by accumulated (and/or migrated) material from intestinum.
- Thymus atrophy and atrophy of spleen follicles indicated immunosuppression (T-cell) (≥50 mg/kg bw/d, 28 day study).

In conclusion,

a) delayed mortalities occurred at ‘irritant’ concentrations/dose levels and

b) other serious health effects occurred at non-irritating concentrations/doses

Both, a) and b) were seen within the critical dose range for STOT RE 2 or R48, respectively, and corresponding C & L with STOT RE 2; H373 and Xn;R48/22 is therefore proposed.

The RAC agreed that ***(Z)-octadec-9-enylamine*** should be classified as STOT RE 2; H373 according to criteria of the EU CLP Regulation (Reg. (EC) 1272/2008) and Xn; R48/22 should be assigned following the criteria of Annex VI to Dir. 67/548/EEC.
Agreement for this proposal was expressed during the public consultation.

Skin corrosion

From the two available studies submitted in CLH report **(*Z)-octadec-9-enylamine*** is to be classified as C; R34 (following the criteria of Annex VI to Dir. 67/548/EEC) and Skin corr. 1B; H314 (EU CLP Regulation). The study reported in the CLH shows symptoms indicative of corrosivity observed between 24 and 72 h after an exposure of 3 minutes.

Agreement for this proposal was expressed during the public consultation.

Respiratory irritation

In an unpublished range finding study, groups of ten male Sprague-Dawley rats were exposed to a vapour of coco alkyl amines ('Armeen C') at mean analytical concentrations of 0.063 and 0.099 mg/L for one hour by whole-body exposure. Chamber concentrations were monitored during the entire one-hour exposure period at a rate of 0.52 L/min. Rats were observed for mortality and signs of toxicity and/or abnormal behaviour throughout the exposure and afterwards daily for 14 days. Body weight was recorded prior to exposure and on day 14. All surviving rats were subjected to a gross necropsy, and the following tissues excised and preserved in 10 % neutral buffer formalin: brain, liver, kidney, heart, pancreas, stomach, lungs, spleen, and testes. Tissues from animals of the 0.099 mg/L group were examined under a light microscope. **There were no deaths, accordingly, the one-hour LC_{50} was found to exceed 0.099 mg/L.** After five minutes of exposure, several rats in the 0.063 mg/L dose group showed cleaning behaviour, but were inactive otherwise. All animals were hypoactive after ten minutes. After 40 minutes, several animals exhibited a slight irritation around the muzzle. This latter effect, as well as hypoactivity in all rats, continued for the remainder of the exposure period. After ten minutes of exposure all rats in the 0.099 mg/L dose group were hypoactive. After 30 minutes, several animals showed signs of irritation, were preening, and exhibited a nasal discharge. At the end of the one-hour exposure, all rats showed mild to severe irritation around the muzzle and had reddish areas on the fur. All rats in both groups exhibited normal appearance and behaviour throughout the 14-day post-exposure observation period. A mean body weight gain in both dose groups was noted at the end of the observation period. No necropsy findings were noted in any rats from both dose groups. Microscopic evaluation of selected tissues from the rats in the 0.099 mg/L dose group included minimal to slight peribronchial lymphoid hyperplasia present in the lung, as well as minimal focal interstitial nephritis in seven of the ten rats, but the latter finding was not rated as a compound-related histomorphologic alteration. All other tissues were within normal histological limits (Hazleton Laboratories America Inc., 1975, cited in: Toxicology Regulatory Services Inc., 2003).
Because of its liquid form read across was applied to ***(Z)-octadec-9-enylamine*** that should be classified as STOT SE 3; H335 (EU CLP Regulation) and Xi; R37 (following the criteria of Annex VI to Dir. 67/548/EEC).

<u>Environmental hazards</u>

The proposal for harmonised classification of the environment of ***(Z)-octadec-9-enylamine*** is based on the data available on the background document (Annex 1). Setting a harmonised

classification for environment is therefore justified to ensure the application of an appropriate classification.

During the elaboration of the CLH dossier technical comments from its public consultation has been accounted. The RAC agrees with the environmental classification proposal (N, R50/53; Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410) and the associated M-factor of 10. This M-factor of 10 is based on the 48h-EC_{50} value of 0.01 mg/L for the invertebrate *Daphnia magna* obtained in a 48 h static study for (Z)-octadec-9-enylamine, after the application of the surrogate approach for the chronic M-factor.

Degradation

Abiotic degradation. No studies on abiotic degradation are available, but hydrolytic degradation is unlikely because of the absence of hydrolysable groups. In general, abiotic degradation processes are expected to be of low significance.

Biodegradation. Screening tests of ready biodegradability (following the OECD 301 guidelines) carried out for ***(Z)-octadec-9-enylamine*** and for the other considered amines, indicate that the pass level criterion for ready biodegradability is reached within 28 days, failing the 10 day window criterion. This might be explained by the reduced bioavailability due to adsorption onto glass surfaces or organic matter, which results in a prolonged lag phase. Additional studies with tallow alkyl amine and coco alkyl amine using activated sludge, have shown that the rates during the exponential part of the degradation curve are comparable with readily degradable substances. This is an indication that the considered substances are degraded by adapted micro-organisms. As the molecular structure is similar for all members of the group, significant differences in degradability are not expected.

The CLP guidance indicates that the 10-day window condition may be waived for complex multi-component substances, including surfactants. This category includes another four multi-component substances, and although measured data are not available, their structure (i.e. an ionic end group and hydrophobic tail) suggests that they will have surface active properties.

Therefore, based on all experimental results available, ***(Z)-octadec-9-enylamine*** is considered to be rapidly degradable and readily biodegradable for the purposes of classification.

Potential for bioaccumulation

Reliable experimental data about bioaccumulation of primary alkyl amines are not available at the moment. Because of their ionic and surface-active properties, it is not possible to experimentally measure their octanol-water partition coefficients (Kow), and the regression equations estimating BCF from log Kow are not suitable. Calculated values of log Kow for the neutral substances in this category are in the range 6.7-7.7 (the log Kow of the protonated form, which will dominate under environmental pHs, will be lower but it is not known by how much; in the absence of data it is assumed to be above 4). However, one experimental study of fish bioconcentration is available for hexadecylamine, as a substance representative of the 5 grouped amines (in terms of molecular weight, chain length, lipophilicity and adsorption) considered in this read-across approach.

Briefly, the test was performed on common carp (*Cyprinus carpio*), without GLPs, according to OECD Guideline 305 with some modifications. Due to adsorption problems, only 50-80% of the nominal concentration (3 µg/L) in the aquaria could be recovered. After an exposure period of 11 months, whole fish concentrations ranged from 1500 to 3600 µg/kg. After removing mucous and scales and washing the fish with chloroform, the residual concentration was 650 to 850 µg/kg. Repeating the rinsing procedure with acidified methanol, the

concentration further dropped to 280-600 µg/kg. This indicates that some of the substance was physically adsorbed (removable with chloroform) with the remainder ionically adsorbed (only removable with acidified methanol). The variable exposure concentration, long study duration and significant adsorption to fish surfaces complicate the interpretation of this study for classification purposes. The importance of skin contamination in terms of chronic toxicity is unknown (it may also vary with fish size and possibly skin condition). The least conservative approach is to assume that the fish were exposed to the nominal concentration in water, and that the substance physically adsorbed to fish surfaces (i.e. before the chloroform rinse) can be ignored as an indicator of possible toxic effects. On this basis, the minimum BCF would be in the range 220-280 L/kg. Lack of information on lipid content means that the values cannot be normalised to a 5% lipid content. However, the dissolved concentration is likely to have been significantly lower than the nominal concentration, and so the BCF will be higher than this calculation suggests (e.g. assuming exposure at 50% of the nominal concentration results in a BCF between 400 and 570 L/kg). Clearly, if whole fish concentrations including skin were included, the BCF would be higher still. Growth in this species over 11 months is likely to have been significant, so the measured fish concentrations may not represent a true steady state either (due to growth dilution). The true BCF is therefore likely to be in the region of 500 L/kg or above.

New information on bioaccumulation was presented by industry during the public consultation. A Critical Body Burden (CBB) approach was used to estimate the BCF for the invertebrate *Daphnia magna* based on 21-day reproduction studies in river water with coco alkyl amines, tallow alkyl amines and (Z)-octadec-9-enylamine, which resulted in an average BCF of 180 L/kg. This approach is not addressed by any technical guidance, and there are some significant uncertainties:

- It is not indicated whether the very low recovery rates (ranging from 20% to 36%) have been accounted for in the *daphnia*-BCF calculations.
- According to the CBB approach, the estimated BCF would depend on the NOEC considered, as lower the NOEC as higher the estimated BCF. The estimated *daphnia*-BCF is based on the NOECrepro of 0.013 mg/L obtained in the study, which is recognised by Industry to be flawed due to the influence of suspended organic matter on bioavailability. Consequently a mitigation factor is applied, resulting in a proposed final NOECrepro of 2.6 µg/L. After reviewing the information on how the mitigation factor has been estimated the true NOECrepro is therefore unknown, and may be lower than this value used for calculations. An assessment of the proposed correction factor is provided in the appendix to the background document.
- The representatively of bioaccumulation in an invertebrate for fish is uncertain (e.g. because of differences in lipid content, metabolic potential, etc.).

The estimated BCF is not considered relevant as an indication of bioaccumulation potential in organisms such as fish.

The 5 substances discussed in this category (as well as hexadecylamine) have molecular weights well below 700 g/mol, so restricted uptake by gills is unlikely.

In summary, a similar bioconcentration potential can be hypothesised for the 5 grouped substances according to their similar physico-chemical properties and molecular structures (there is no experimental information on metabolism in fish, but differences in rates of metabolism are likely to be minor since they are all considered “rapidly degradable”).The experimental study of bioaccumulation in fish for the representative substance

hexadecylamine suggests that the realistic worst case BCF will be above 500 for each of the five substances considered.

Ecotoxicity

Due to specific physico-chemical properties of the five grouped substances under consideration, they rank among the group of difficult substances in aquatic toxicity testing, particularly: practically insoluble in water and a strong tendency to adsorb on surfaces such as test vessels or organic material.

Although acute ecotoxicity data are available for four of the substances separately for all three trophic levels, based on their similarity in terms of physicho-chemical properties, common functional groups and common metabolic breakdown products, as well as interpretational issues related to the difficulty of testing, lowest values have been selected from the ecotoxicity database to represent the entire category. Most of the acute aquatic toxicity results for the 5 grouped substances considered in this category are below 1 mg/l for the three aquatic taxonomic groups.

Aquatic vertebrates. The lowest well documented 96-h LC_{50} reported for fish is 0.11 mg/L (nominal) for (*Z*)-octadec-9-enylamine to *Pimephales promelas*. A static test system was used, and concentrations decreased rapidly showing a rather wide spread of recovery rates (probably due to adsorption onto walls of test vessels, organisms and dissolved organic matter). Taking into account the indicated mean recovery rate (about 51%) considered, the 96-h LC_{50} for fish can be estimated to be 0.06 mg/L.

No long-term data are available for fish.

Aquatic invertebrates. The lowest short-term result for *Daphnia magna* was a 48-h EC_{50} of 0.011 mg/L for (*Z*)-octadec-9-enylamine, based on nominal concentrations. Again, the test substance concentration (measured at 0 h and 48 h) decreased strongly showing a wide spread of recovery rates (recovery 48-118%, mean value 81%). Due to this uncertainty, no calculations were made using mean measured concentrations to estimate real concentrations.

Regarding long-term toxicity data, 21-d *Daphnia magna* reproduction studies are available for coco alkyl amines, tallow alkyl amines and (Z)-octadec-9-enylamine. A 21-d NOEC of 0.013 mg/l was estimated based on nominal concentrations. However, the dilution water contained a high level of suspended matter and humic acid, so this will not represent truly dissolved concentrations. Analytical measurement (without filtration) showed that total concentrations decreased at the end of the test and recovery rates varied strongly. It is also noted that the reported NOEC is slightly higher than the lowest 48-h EC_{50} for this species, and is therefore, likely to be an overestimation. According to the Critical Body Burden approach, presented during the public consultation, and to compensate the influence of the river characteristics, Industry applied a correction factor of 5 proposing a final NOECrepro of 2.6 µg/L. After reviewing the information on how this correction factor has been calculated, it is considered insufficiently justified (see also Appendix to the background document). The true NOECrepro is therefore unknown, and may be lower than this value suggests. Due to this uncertainty, this study has limited usefulness for the purposes of classification.

Algae. The lowest short-term result for algae is a 72-h ErC50 of 0.083 mg/L on *Scenedesmus subspicatus* for tallow alkyl amine, based on nominal concentrations (no analytical measurements were taken).

Regarding long-term, the lowest long-term result is a 96-h NOEC of 0.01 mg/L on *Selenastrum capricornutum* for (*Z*)-octadec-9-enylamine, based on nominal concentrations. It is indicated that measured concentrations decreased strongly during the test period, so the real

exposure concentrations may have been lower and this result is of limited usefulness for the purposes of classification.

Conclusion on environmental classification

Classification according to CLP

Acute aquatic hazard
The lowest reliable short-term aquatic toxicity result for this category is a 48-h EC_{50} of 0.011 mg/L for *Daphnia magna* based on nominal concentrations for (Z)-octadec-9-enylamine (due to the lack of recovery rates it is expected the real EC_{50} to be lower). Therefore, ***(Z)-octadec-9-enylamine*** is classifiable as Aquatic Acute 1 (H400). Since this toxicity value is in the range 0.01- 0.1 mg/L, the M-factor (Acute) applied would be 10.

Chronic aquatic hazard
Two different approaches are included, both justifying the same result:

Two long-term results are available (for invertebrates and algae), both of which give NOECs of 0.01 mg/l or lower. Therefore, the substance is classifiable as Aquatic Chronic 1 (H410) based on toxicity information. The rapid degradability of the substance affects the M-factor, but since it is unclear how much lower the true NOECs might be (the behaviour of the substance and experimental designs mean that the true exposure concentrations are unknown) it not considered relevant to set an M-factor based on these data.
As fully reliable chronic toxicity data are not available for any of the three trophic levels, the surrogate approach can be applied, based on acute effects and fate properties. The lowest acute L(E)C50s for all three trophic groups are in the range 0.01 - 0.1 mg/l, and the realistic worst case BCF is > 500 for fish, based on the study for hexadecylamine as representative substance (and the estimated log Kow > 4). Consequently, (**Z)-octadec-9-enylamine** fulfils the criteria for classification as Aquatic Chronic 1 (H410).
The M-factor (chronic) is 10, according to the surrogate approach, based on the acute toxicity data.

Classification according to the DSD criteria

As proposed by the dossier submitter, the RAC agrees that classification as **N; R50/53** (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment) is adequate, because although the amines in question including ***(Z)-octadec-9-enylamine*** are readily biodegradable, they have BCFs for fish above 100, and a 48-h EC_{50} of 0.011 mg/L for *Daphnia magna*. The following specific concentration limits should be applied:

Classification	Concentration
N; R50/53	$C \geq 2.5\%$
N; R51/53	$0.25\% \leq C < 2.5\%$
R52/53	$0.025\% \leq C < 0.25\%$

Where C is the concentration of ***(Z)-octadec-9-enylamine***.

Additional information

The Background Document, attached as Annex 1, gives the detailed scientific grounds for the Opinion.

ANNEXES:

Annex 1	Background Document (BD)[1]
Annex 2	Comments received on the CLH report, response to comments provided by the dossier submitter and rapporteurs' comments (excl. confidential information)

[1] The Background Document (BD) supporting the opinion contains scientific justifications for the CLH proposal. The BD is based on the CLH report prepared by a dossier submitter.