Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine

Product type: 8

ECHA/BPC/270/2020

Adopted

2 December 2020

Opinion of the Biocidal Products Committee

on the application for approval of the active substance N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine for product type 8

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the application for approval in product type 8 of the following active substance:

Common name:	**N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine**
Chemical name:	**N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine**
EC No.:	**219-145-8**
CAS No.:	**2372-82-9**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Lonza GmbH, on 2004, the evaluating Competent Authority Portugal submitted an assessment report and the conclusions of its evaluation to the Commission on 9 November 2005. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the Technical Meeting (TMIII06 on 16-19 October 2006 and TMIV2010 on 22-26 November 2010, BPC and its Working Groups (WGV 2016 on 22-23 November 2016 (Human Health) and WGI2020 on 23-24 March 2020 (Human Health). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Portugal

The BPC opinion on the application for approval of the active substance N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine in product type 8 was adopted on 2 December 2020.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority positions including their grounds are published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine in product type 8 may not be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine in product type 8**.** Specifications for the reference source are established with a minimum purity of 91% w/w, no relevant impurities were considered.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are available for the relevant matrices (soil and water). It was not possible to fully validate an analytical method covering drinking water samples in accordance with 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 guidelines at the required limit of 0.1 µg/L but only at ≥ 1 µg/L due to chlorine interference (coming from the water itself). The method was also tested with purified water and the LOQ achieved was 0.1 µg/L.

The active substance is not volatile in air as its vapour pressure is low. In addition in the wood protection market, the product is sold as an aqueous solution of the a.s. and will not be used by spraying application; thus measurable concentrations in the air under normal use will not occur and are highly unlikely even under unusual circumstances (e.g. accidental releases). Thus, it is considered that the determination of analytical methods in air is not required.

As N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine is not classified as toxic or highly toxic, analytical methods for human body fluids and tissues are not required.

Wood treated with the a.s. in a biocidal product is not intended for use in areas where food for human consumption is prepared, consumed or stored, or where the feedingstuff for livestock is prepared, consumed or stored or come into direct contact with food producing animals. Thus, it is considered that analytical methods for determination of residues in/on food or feedstuffs are not required.

No harmonized classification is available. The proposed classification and labelling for N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 3 Skin Corr. 1B STOT RE 2 Acute Aquatic 1
Labelling	
Pictogram codes	GHS05, GHS06, GHS08, GHS09
Signal Word	Danger
Hazard Statement Codes	H301 H314 H373 H400
Specific Concentration limits, M-Factors	M = 1
Justification for the proposal	
Acute Tox. 3 H301: Toxic if swallowed, based on the oral LD50 in rats of 261 mg a.s./kg bw. Because of the corrosive effects of the undiluted product Skin Corr. 1B, H314: Causes severe skin burns and eye damage is assigned. The risk of severe damage to eyes is considered implicit. STOT RE 2, GHS08, H373: May cause damage to organs through prolonged or repeated oral exposure. (nephrotoxicity: moderate proximal tubular changes with evidence of degeneration, regeneration and hyperplasia at 90 mg/kg bw/day). Acute Aquatic 1; H400: Very Toxic to aquatic life based on the EbC50 of 0.012 mg/l on the most sensitive aquatic organism tested (algae); active ingredient can be considered as readily biodegradable and does not merit additional classification for chronic effects to aquatic life.	

b) Intended use, target species and effectiveness

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine is intended to be used as an active substance against wood destroying basidiomycetes, with preventive protection of wood and construction timbers of use classes (UC) 1 to 4a. The active substance was considered in the assessment for use in industrial pre-treatment of timber by vacuum pressure impregnation and dipping/surface treatment.

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine is a non-ionic surfactant type active ingredient. Since it is surface active, it has fair wetting properties and reacts strongly with cell walls of micro organisms. Its mode of action, therefore, is to destroy the cell walls by chemical reaction with the exterior structures and by entering and disintegrating the inner phospholipid-bilayer based membrane structures. Due to its interaction with phospholipid-bilayer structures, it severely alters the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms and may facilitate the uptake of other biocides. It is effective against Gram+ bacteria. Weak activity is shown against Gram- bacteria, and there is a selective activity spectrum against fungi.

It can be concluded that N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine has demonstrated sufficient efficacy in the preventive control of wood destroying basidiomycetes. It has also showed a sufficient level of efficacy to protect constructional timbers in areas with moderate or subtropical climate and is to be used exclusively in industrial applications.

No resistance of fungi from treated wood has been observed. N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine is used in combination with another active (Propiconazole) so that a resistance development seems to be extremely unlikely

c) Overall conclusion of the evaluation including need for risk management measures

Human health

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine, has a rate and extent of oral absorption of 2.5% based on excretion via urine, and limited metabolism, the rate and extent of dermal absorption was 2% for a aqueous solution (0.1% w/w active substance in aqueous solution) and 2.5% for in-use dilution (0.025 % w/w active substances in use dilutions). The distribution was mainly in kidney, lung, pancreas, salivary gland, small intestine mucosa, spleen and stomach mucosa. A potential for accumulation in the renal tubule was identified. The rate and extent of excretion was >90% of the radiolabelled substance and was excreted in faeces, 0.2% in urine, 0.3% in CO_2 (5 days after dosing). Acute toxicity studies resulted in a LD50 of 261mg/kg bw/day and N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine was corrosive (3-minutes applicancation). Repeated dose toxicity studies in rats showed histopathological changes in the small intestine and mesenteric lymph node and nephrotoxicity (the latter at highest tested doses). In the combined long term carcinogencity study the No Observed Adverse Effect Level (NOAEL) could not be identified based on adverse effects at lowest doses tested in the mesenteric lymph node and in kidneys).

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine was not mutagenic or clastogenic in *in vivo* studies, and with no carcinogenic potential. For reproductive toxicityfor rats a lower mean epidimydes weight, lower seminal vesicle weights and mean absolute testes weight at both generations at the maximum dose tested was found. For rabbits at the highest dose tested an increased incidence for early, late and total resorptions was found. Accumulation of macrophages with vacuolized (foamy) cytoplasm in the mesenteric lymph node was considered as primary adverse effect, occurring at different doses with a dose response relationship, and seen in several studies of different duration (repeated dose studies and combined long term carcinogenicity study). The histopathological changes in the mesenteric lymph node were considered relevant for humans and thus, these have been identified as the critical effect for the derivation of the Acceptable Exposure Level for the long-term and medium-term time frame (AEL long-term: 0.00025 mg/kg bw/day; AEL medium-term: 0.0004 mg/kg bw/day). The effects occurring in the developmental toxicity study in rabbit were considered relevant for the derivation of the Acceptable Exposure Level for the short-term time frame (AEL short-term: 0.0023 mg/kg bw/day).

Due to the corrosive effects of the substance occurring via the oral and dermal route a No Observed Adverse Effect Concentration (NOAEC) for oral route (NOAEC oral 0.03%) and a Lowest Observed Adverse Effect Concentration (LOAEC) for the dermal route (LOAEC dermal 0.25%) were derived and used, where relevant, in the risk assessment to account for local effects.

The exposure estimations have been conducted according to the exposure scenario available in biocides guidance documents based on pattern of uses considered to be a realistic worst case. The exposure estimations of industrial users are compared with the long-term AEL, assuming a chronic exposure of the workers, who would perform their task on daily basis. Exposure occurring during cleaning and maintenance (scenario 5) is compared to the medium-term AEL since it can be assumed that this task takes place only once or twice per year. The exposure via timber treatment (application phase) is considered as primary exposure, whereas restacking fallen treated timber (scenario 6) will normally be undertaken by a person other than the person who is undertaking the actual dipping of the wood. This exposure is considered as secondary.

The exposure for an industrial user from the use of the product during short-term dipping, dipping and vacuum pressure treatment application use class 4a are concluded to result in unacceptable risk also when appropriate PPE (coverall and gloves) is worn. The exposure for an industrial user from the use of the product during vacuum pressure treatment application use classes 2 and 3 are concluded to result in unacceptable risk also when appropriate PPE is worn. Industrial users can be exposed up to twice a year to the product during cleaning and maintenance of dipping tanks as used for dipping treatment and of solution reservoir, as used for vacuum pressure treatment. The exposure for an industrial user to the product during cleaning of dipping tanks result in unacceptable risk also when appropriate PPE (coverall and gloves) are worn. However, for an industrial user exposed during cleaning and maintenance of solution reservoir, as used for vacuum pressure treatment the exposure result in acceptable risk when appropriate PPE (coverall and gloves) are worn.

The exposure calculation for the scenario of restacking fallen treated timber (scenario 6) leads to acceptable risk for this task when appropriate PPE (coverall and gloves) is worn. Combined exposure for treatment application and restacking fallen treated timber is not considered relevant since normally both tasks are undertaken by different persons.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Automated short-term dipping application	Primary exposure - Automated short-term dipping application). PPE: gloves and coveralls.	Industrial users	Not acceptable
Automated dipping application	Primary exposure - Automated dipping application. PPE: gloves and coveralls.	Industrial users	Not acceptable
Vacuum pressure treatment application HC 2 & 3)	Primary exposure – vacuum pressure treatment of wooden articles PPE: gloves and coveralls.	Industrial users	Not acceptable
Vacuum pressure treatment application HC 4a)	Primary exposure – vacuum pressure treatment of wooden articles. PPE: gloves and coveralls.	Industrial users	Not acceptable
Cleaning and maintenance-dipping application	Primary exposure – cleaning of treatment equipment PPE: gloves and coveralls.	Industrial users	Not acceptable
Cleaning and maintenance-vacuum pressure treatment	Primary exposure – cleaning and maintenance of treatment equipment PPE: gloves and coveralls.	Industrial users	Acceptable with PPE
Restacking fallen treated timber	Secondary exposure – restacking of fallen timber treated PPE: gloves and coveralls.	Industrial users	Acceptable with PPE
Chewing treated wood off-cuts	Secondary exposure – a toddler or an infant ingests residues through mouthing treated wood off-cuts	General public (toddlers and infants)	Acceptable
Playing on (weathered) playground structures	Secondary exposure – dermal and ingestion exposure of a toddler or an infant playing on treated wood structures	General public (toddlers and infants)	Not acceptable
Vapour release from wood use indoor	Secondary exposure – inhalation exposure of a toddler playing on treated wood structures	General public (toddlers)	Acceptable

Sanding treated wood from vacuum pressure impregnated timber	Secondary exposue – Adults (non-professionls): sanding treated wood (inhalation and dermal exposure) from vacuum pressure impregnated timber (acute exposure) Adults (professionals): sanding treated wood (inhalation and dermal exposure) from vacuum pressure imprenated timber (chronic exposure)	General public (non-professionals adults)	Acceptable
		General public (professionals – adults)	Acceptable

An unacceptable risk has been identified for industrial users, short term dipping application/ surface treatment, dipping application and vacuum pressure treatment, even when gloves and coveralls are worn.

With respect to secondary exposure for the scenario playing on (weathered) playground structures for infants and toddlers, an unacceptable risk was identified. This scenario may be refined at product authorisation.

Environment

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine is a surfactant substance and has been demonstrated to be readily biodegradable under biotic conditions as it was extensively degraded in the relevant biodegradability tests. Furthermore, it is strongly adsorbed to soil with overall Koc values of 26 000 to 551 000 cm^3/g and therefore has a very low leaching potential to groundwater. The substance is stable to photolysis, very soluble in water and hydrolytically stable under relevant environmental conditions.

The very low vapour pressure (5.45×10^{-5} Pa at 25 ºC) indicates that N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine has a low tendency to volatilize. Therefore, air has not been considered as a compartment of concern. It has a low potential to bioaccumulate in aquatic or terrestrial species given the estimated partition coefficient of 0.7 (log Pow of 0.16). Physico-chemical properties have been used as waivers for soil and aquatic persistence studies.

The proposed intended uses are restricted to industrial preventive treatments conducted by the following process: open tank, dipping surface, dipping and vacuum/pressure. Environmental exposure has been addressed through industrial use emissions and emmissions from wood in service. Applicable exposure routes have been considered (see summary table).

As a result of the industrial treatment and wood in service (noise barrier) emissions to Sewage Treatment Plants (STPs) may occur, and indirectly the substance can be released to the surface water and sediment. As result of the use of treated wood in service (jetty lake and sheet piling waterway) direct emissions to surface water may occur. As result of the intended uses of the industrial process and from wood in service emissions to soil may occur.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Industrial Immersion treatment - Dipping	Industrial preventive treatment; exposure of sewage treatment plant (STP) and surface waters from draining facilities after application and during storage	Unacceptable risk identified for the soil compartment (long term), STP and aquatic environment. Acceptable if application process is carried out within a contained area, not connected to the surface water drainage or to STP, situated on impermeable hard standing with bonding to prevent run-off; storage place must be paved with impermeable material and covered.
Industrial Immersion treatment - Open tank	Industrial preventive treatment; exposure of STP and surface waters from draining facilities after application and during storage.	Unacceptable risk identified for the soil compartment (long term), STP and aquatic environment. Acceptable if application process is carried out within a contained area, not connected to the surface water drainage or to STP, situated on impermeable hard standing with bonding to prevent run-off; storage place must be paved with impermeable material and covered.
Industrial Vacuum pressure	Industrial preventive treatment; exposure of STP and surface waters from draining facilities after application and during storage.	Unacceptable risks identifiied for the soil compartment (long term), STP and aquatic environment (except sediment organisms). Acceptable if application process is carried out within a contained area, not connected to the surface water drainage or to STP, situated on impermeable hard standing with bonding to prevent run-off; storage place must be paved with impermeable material and covered.

Wood in service - Noise barrier – Use class 3	Wood in service. Noise barriers located in roadsides; exposure to soil and to STP via drainage systems and the aquatic environment	Unacceptable risks identified for the soil compartment (long term); after refinement of exposure by consideration of extended size of the receiving soil compartment no unacceptable risks were identified. No unnacceptable risks for STP or aquatic environment identified.
Wood in service - House – Use class 3	Wood in service. Possible exposure to soil via leaching from wood in place; permanently exposed to wetting.	Unacceptable risks identified for the soil compartment (long term); after refinement of exposure by consideration of extended size receiving soil the use will not pose unacceptable risks to the soil compartment.
Wood in service - Transmission pole – Use class 3	Wood in service. Possible exposure to soil via leaching from wood in place permanently exposed to wetting	No unacceptable risks identified for the soil compartment.
Wood in service - Fence post – Use class 3	Wood in service. Possible exposure to soil via leaching from wood in place permanently exposed to wetting	No unacceptable risks identified for the soil compartment.
Wood in service - Jetty in lake – Use class 4a	Wood in service. Exposure to surface waters	Considering the minor exceedance of the predicted no-effect concentration (PNEC) value and taking into account N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine is readily biodegradable risks were considered acceptable.
Wood in service - Sheet piling waterway – Use class 4b	Wood in service. Exposure to surface waters and sediment	Considering the minor exceedance of the PNEC value and taking into account N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine is readily biodegradable, risks were considered acceptable.

Unacceptable risks were identified for STP, aquatic organisms, sediment organisms and the terrestrial compartment for all treatments at industrial level. However, these can be addressed with appropriate risk management measures, as follows: emissions can be avoided if the application process is carried out within a contained area, not connected to the surface water drainage or to STP. It should be situated on impermeable hard standing, with bonding to prevent run-off and a recovery system should be used. The storage place must be paved with impermeable material and covered. For the terrestrial compartment the exposure was further refined by considering an extended size of receiving soil and resulted in acceptable risk. No risk management measures are needed.

Unacceptable risks (long term) were identified for the terrestrial (soil) compartment for treated wood in service in the modalities noise barrier and house. However, after refinement of exposure the risk was considered acceptable. No risk management measures are needed.

Unacceptable risks were identified for the surface waters for treated wood in service in permanent contact with water – jetty lake and sheet piling waterway modalities. However, as PEC/PNEC values were close to 1 and N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine is readily biodegradable and dissipating from the aquatic environment the risk was considered acceptable. No risk management measures are needed. No risk was identified for the sediment organisms from the jety lake and sheet piling waterway scenarios.

Acceptable risks were identified for the terrestrial compartment (soil) as the only relevant exposure scenario for treated wood in service used as transmission posts or fence poles. No risk management measures are needed.

Based on the high soprtion capacity so that once adsobed, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine will be relatively immobile in soil, and considering that the available model for calculating the concentration in groundwater at the time of the evaluation was not fully appropriate, it was considered that no groundwater assessment is required.

Overall conclusion

An unacceptable risk for N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine has been identified for industrial users, short term dipping application/surface treatment, dipping application and vacuum pressure treatment, even when gloves and coveralls are worn.

For the environment for industrial processes (open tank, dipping and vacuum pressure treatment) the use of N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine will not pose unacceptable risks for the environmental compartments as long as appropriate risk management measures are considered. The treated wood in service for all use classes (considering the scenarios for fence, house, noise barrier, transmission pole, fence post, jetty in lake and sheet piling waterway) will not pose unacceptable risks for the environment.

Therefore, combining the assessment for human health and the environment, no safe use can be identified due to unacceptable risks identified for industrial users, even when risk mitigation measures are applied.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	no classification required	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P and not vP	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B and not vB	
	Toxic (T)	T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No conclusion can be drawn based on the available data.	No conclusion can be drawn whether N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine fulfils criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No conclusion can be drawn based on the available data.	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required.		
Concerns linked to critical effects other than those related to endocrine disrupting properties	For N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine no concerns regarding critical effects according to Article 10(1)(e) are identified.		
Proportion of non-active isomers or impurities	Not applicable as N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine does not have isomers or relevant impurities.		

Consequently, the following is concluded:

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012 and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[1], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[2] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment[3]" agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn on the available data: N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine does not meet the ED criteria for T modality, however the EAS mediated parameters have not been sufficiently investigated; hence, no conclusion on the ED properties can be drawn for human health according to the criteria laid down in Regulation (EU) 2017/2100. This is also the case for non-target organisms as ED properties could not not sufficiently be addressed with the available data. For reports submitted before 1 September 2013, it is mentioned in the CA meeting note mentioned above that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of diamine for PT 8 was submitted before 1 September 2013.

2.2.2. POP criteria

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine does not fulfil the criteria for being considered as a POP substance as it is not persistent and does not have a bioaccumulation potential.

2.3. BPC opinion on the application for approval of the active substance N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine in product type 8

In view of the evaluation, it is concluded that biocidal products containing N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine used for wood preservation may not be expected to meet the criteria laid down in point (b)(iii) of Article 19(1) of Regulation (EU) 528/2012. Consequently, it is proposed that N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine shall not be approved and included in the Union list of approved active substances.

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[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

[2] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

[3] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).