



Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	A mixture of: N,N'-ethane-1,2-diylbis(decanamide); 12-hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide; N,N'-ethane-1,2-diylbis(12-hydroxyoctadecanamide)
EC Number:	430-050-2
CAS Number:	-
Authority:	Ministry of Agriculture, Food and Environment (Spain)
Date:	21/03/2017

Cover Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	A mixture of: N,N'-ethane-1,2-diylbis(decanamide); 12-hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide; N,N'-ethane-1,2-diylbis(12-hydroxyoctadecanamide)
IUPAC name (public):	-
Index number in Annex VI of the CLP Regulation:	616-127-00-5
Molecular formula:	N/A
Molecular weight or molecular weight range:	N/A
Synonyms:	<p>12-Hydroxy-<i>N</i>-[2-[1-oxydecyl)amino]ethyl]octadecanamide 12-Hydroxy-<i>N</i>-[2-[1-oxydecyl)amino]ethyl]octadecanamide <i>N,N'</i>-Ethane-1,2-diylbis(12-hydroxyoctadecanamide) A mixture of: <i>N,N'</i>-ethane-1,2-diylbis(decanamide); 12-hydroxy-<i>N</i>-[2-[1-oxydecyl)amino]ethyl]octadecanamide; <i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) A mixture of: <i>N,N'</i>-ethane-1,2-diylbis(decanamide); 12-hydroxy-<i>N</i>-[2-[1-oxydecyl)amino]ethyl]octadecanamide; <i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) <i>N,N'</i>-Ethane-1,2-diylbis(12-hydroxyoctadecanamide) reaction mass of: <i>N,N'</i>-Ethane-1,2-diylbis(decanamide) reaction mass of: <i>N,N'</i>-Ethane-1,2-diylbis(decanamide) reaction mass of: <i>N,N'</i>-Ethane-1,2-diylbis(decanamide) A mixture of: <i>N,N'</i>-ethane-1,2-diylbis(decanamide); 12-hydroxy-<i>N</i>-[2-[1-oxydecyl)amino]ethyl]octadecanamide; <i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) Diamid wax mixture~ Reaction mass of <i>N,N'</i>-ethane-1,2-diylbis(alkanamide), 12-hydroxy-<i>N</i>-[2-[1-oxyalkyl)amino]ethyl]octadecanamide and <i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) Reaction mass of <i>N,N'</i>-ethane-1,2-diylbis(alkanamide), 12-hydroxy-<i>N</i>-[2-[1-oxyalkyl)amino]ethyl]octadecanamide and <i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) THIXATROL PLUS, THIXATROLPLUS, AD-2000, DISPARLON 6200, THIXATROL PLUS</p>

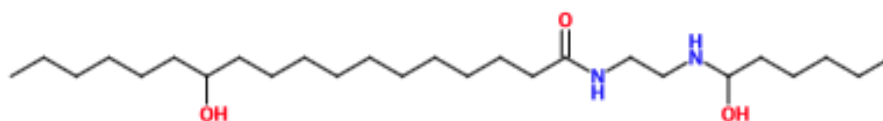
Type of substance Mono-constituent Multi-constituent UVCB

Structural formula: The substance is a multiconstituent. There is no information on the structural formulas of the constituents on the ECHA dissemination site.

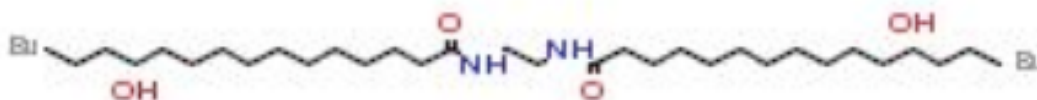
1.2 Similar substances/grouping possibilities

The substances in the below tables are structurally similar with A mixture of: N,N'-ethane-1,2-diylbis(decanamide); 12-hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide; N,N'-ethane-1,2-diylbis(12-hydroxyoctadecanamide).

Public name:	12-hydroxy-N-[2-[(1-oxyhexyl)amino]ethyl]octadecanamide
EC name (public):	12-hydroxy-N-[2-[(1-oxyhexyl)amino]ethyl]octadecanamide
EC number:	432-430-3
CAS number:	-
IUPAC name (public):	
Index number in Annex VI of the CLP Regulation:	616-200-00-1
Molecular formula:	-
Molecular weight or molecular weight range:	-
Synonyms:	<p><i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) Reaction mass of <i>N,N'</i>-ethane-1,2-diylbis(hexanamide) and 12-hydroxy-N-[2-[(1-oxyhexyl)amino]ethyl]octadecanamide and <i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) Reaction mass of: <i>N,N'</i>-ethane-1,2-diylbis(hexanamide) Reaction mass of <i>N,N'</i>-ethane-1,2-diylbis(hexanamide) and 12-hydroxy-N-[2-[(1-oxyhexyl)amino]ethyl]octadecanamide and <i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) 12-hydroxy-N-[2-[(1-oxyhexyl)amino]ethyl]octadecanamide Complex mixture of diamide waxes <i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) Reaction mass of <i>N,N'</i>-ethane-1,2-diylbis(hexanamide); 12-hydroxy-N-[2-[(1-oxyhexyl)amino]ethyl]octadecanamide; <i>N,N'</i>-ethane-1,2-diylbis(12-hydroxyoctadecanamide) Reaction mass of: <i>N,N'</i>-ethane-1,2-diylbis(hexanamide) Thixatrol MAX ThixatrolMAX EA2854</p>

Structural formula:

Public name:	N,N'-ethane-1,2-diylbis(12-hydroxyoctadecan-1-amide)
EC name (public):	N,N'-ethane-1,2-diylbis(12-hydroxyoctadecan-1-amide)
EC number:	204-613-6
CAS number:	123-26-2
IUPAC name (public):	N,N'-ethane-1,2-diylbis(12-hydroxyoctadecanamide)
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	C ₃₈ H ₇₆ N ₂ O ₄
Molecular weight or molecular weight range:	625.021
Synonyms:	<i>Octadecanamide, N,N'-1,2-ethanediylbis 12-hydroxy-</i> <i>Octadecanamide, N,N'-1,2-ethanediylbis[12-hydroxy-</i> <i>1,2-ethylene bis(12-hydroxystearamide)</i> <i>Bisamide</i> <i>N,N'-ethane-1,2-diylbis(12-hydroxyoctadecanamide)</i>

Structural formula:

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
Restriction	<input type="checkbox"/> Annex XVII	
Harmonised C&L	<input checked="" type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input checked="" type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs) (Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)	
Further details		

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
616-127-00-5	reaction mass of: N,N'-Ethane-1,2-diylbis(decanamide) 12-Hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide N,N'-Ethane-1,2-diylbis(12-hydroxyoctadecanamide)	430-050-2	-	Skin Sens. 1 Aquatic Chronic 2	H317 H411	-	-

3.1.2 Self classification

- In the registration:
 - Aquatic Acute 1, H400
 - Aquatic Chronic 1, H410, M-chronic=100
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - No additional hazard classes.

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
<input type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa
<input type="checkbox"/> 1000 - 10,000 tpa	<input type="checkbox"/> 10,000 - 100,000 tpa	<input type="checkbox"/> 100,000 - 1,000,000 tpa
<input type="checkbox"/> 1,000,000 - 10,000,000 tpa	<input type="checkbox"/> 10,000,000 - 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input checked="" type="checkbox"/> Confidential
Registered as NONS.		
2 individual submissions out of which 1 is active and 1 is inactive currently.		
The substance is manufactured and/or imported in the European Economic Area, but tonnage data is confidential.		

4.2 Overview of uses

There is no information on the uses of the substance on the ECHA dissemination site.

Based on information found on the internet ([http://www.elementis-specialties.com/esweb/webproducts.nsf/allbydocid/8885CC873FA666DE8525799C004AC223/\\$FILE/ELEMENTIS-THIXATROL%20PLUS.pdf](http://www.elementis-specialties.com/esweb/webproducts.nsf/allbydocid/8885CC873FA666DE8525799C004AC223/$FILE/ELEMENTIS-THIXATROL%20PLUS.pdf)), THIXATROL PLUS can be used as a rheological additive in coatings, paints, adhesives, sealants and two component polyurethane systems. Typical levels of use range from 0.2% to 2.0% of the total system weight. Therefore, it seems that widedispersive uses could take place.

¹ Based on ECHA dissemination site accessed on 11 October 2016.

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disrupter
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

5.3. Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ²	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

² CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Potential PBT concern:

There is a concern on the potential PBT properties of the substance.

Persistence:

There is only one test on ready biodegradability of the substance available. In the test, 69 % degradation was reached after 28 days without fulfilling the 10-day window. In addition, a ready biodegradability test with a read across substance has been provided which resulted in 20 % degradation after 28 days. As the registered substance is a multiconstituent, the degradability of the individual constituents cannot be confirmed based on the available information. Therefore, further information on the degradation of individual constituents is needed to conclude on their persistence.

Bioaccumulation:

There is no experimental information on the bioaccumulation of the substance or its constituents. Log Kow of the substance measured using the HPLC-method is in the range of 5.4-6.6. (at 25°C). Hence, the substance and its constituents fulfill the screening criteria for B/vB.

Toxicity:

The chronic toxicity value (NOEC) of algae reported for the substance is 0.003 mg/L. Therefore, it seems that the substance fulfills the criteria for T. Additionally, there is no information on the toxicity of individual constituents.

Exposure concern:

The substance is self-classified by the notifier as Aquatic Chronic 1 with an M-factor of 100. Based on the available information on the internet on potential uses of the substance, exposure of environment could take place.

5.4. Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p>In order to be able to conclude on the persistence of the constituents, screening tests and/or degradation simulation studies on the (most relevant) constituents are needed. If P/vP is confirmed, information on the bioaccumulation of the relevant constituents should be requested. Further information on the ecotoxicity of the relevant constituents may also be needed.</p> <p>Information for the environmental exposure assessment of the substance should be provided.</p>	

5.5. Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>This section will be clarified after the clarification of the concerns.</p> <p>If the PBT concern is confirmed, a risk management options analysis shall be carried out. Potential follow-up options are authorisation and/or restriction.</p>			