

## Justification for the selection of a substance for CoRAP inclusion

<b>Substance Name (Public Name):</b>	10-undecenyl 2-cyano-3,3-diphenylpropenoate
<b>Chemical Group:</b>	-
<b>EC Number:</b>	700-604-0 (List number)
<b>CAS Number:</b>	947701-81-7
<b>Submitted by:</b>	Finland
<b>Published:</b>	26/03/2014

### 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

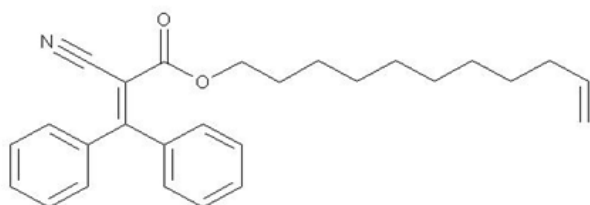
### 1.1 Other identifiers of the substance

Table 1: Substance identity

<b>EC name:</b>	
<b>IUPAC name:</b>	10-undecenyl 2-cyano-3,3-diphenylpropenoate
<b>Index number in Annex VI of the CLP Regulation</b>	No harmonized classification
<b>Molecular formula:</b>	C <sub>27</sub> H <sub>31</sub> O <sub>2</sub> N
<b>Molecular weight or molecular weight range:</b>	402
<b>Synonyms/Trade names:</b>	Undec-10-en-1-yl 2-cyano-3,3-diphenylacrylate 2-Propenoic acid, 2-cyano-3,3-diphenyl-, 10-undecen-1-yl ester (CAS-name) Undecenyl crylene (UC)

**Type of substance**     Mono-constituent     Multi-constituent     UVCB

**Structural formula:**



## 1.2 Similar substances/grouping possibilities

Read across to ethylhexyl methoxycrylene (EHMC) and undecyl methoxycrylene is used in the registration dossier.

The substance is similar to octocrilene (EC 228-250-8), which is included in the CoRAP and evaluated by France in 2012.

<b>EC name:</b>	
<b>EC number</b>	700-213-5
<b>CAS number</b>	947753-66-4
<b>IUPAC name:</b>	Ethylhexyl methoxycrylene (EHMC)
<b>Index number in Annex VI of the CLP Regulation</b>	
<b>Molecular formula:</b>	
<b>Molecular weight or molecular weight range:</b>	391.51
<b>Synonyms/Trade names:</b>	CAS Name: 2-propenoic acid, 2-cyano-3-(4-methoxyphenyl)-3-phenyl-, 2-ethylhexyl ester

<b>EC name:</b>	
<b>EC number</b>	700-824-2
<b>CAS number</b>	947701-81-7
<b>IUPAC name:</b>	Undecenyl methoxycrylene
<b>Index number in Annex VI of the CLP Regulation</b>	
<b>Molecular formula:</b>	
<b>Molecular weight or molecular weight range:</b>	391.51
<b>Synonyms/Trade names:</b>	CAS name: 2-Propenic acid, 2-cyano-3-(4-methoxyphenyl)-3-phenyl, 10-undec-1-yl ester

## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

No classification.

### 2.2 Self classification

- In the registration

Not classified

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Not notified in the C&L Inventory.

### 2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No proposals.

## 3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input checked="" 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 type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p>Undecenyl crylene is used as a cosmetic ingredient within sunscreen applications/lotion.</p> <p>Tonnage band is 1-10 per annum.</p> <p>PROC 3: Use in closed batch process (synthesis or formulation)</p> <p>PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)</p> <p>PC 32: Polymer preparations and compounds</p> <p>PC 39: Cosmetics, personal care products</p>			

## 4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

### 4.1 Legal basis for the proposal

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

### 4.2 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

### 4.3 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 <sup>1</sup> <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 <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input 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)

<sup>1</sup> 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

Undecenyl crylene (UC) was selected based on suspected PBT/vPvB properties. Due to use in ordinary consumer products (sunscreen lotion) the substance is estimated to have wide dispersive use.

Most of the physical-chemical properties are based on read across to ethylhexyl methoxycrylene (EHMC) and undecenyl methoxycrylene. All aquatic ecotoxicological studies (algae and long-term Daphnia test) have been conducted with EHMC due to low water solubility of undecenyl crylene (0.000872 mg/L).

The substance has a high octanol - water partition coefficient with a  $\log P_{ow} > 6.5$  which suggests that the substance may have bioaccumulation potential. In the ready biodegradation study undecenyl crylene achieved 3 % biodegradation after 28 days. The study shows that it is not readily biodegradable and therefore fulfills the P screening criteria. NOEC for Daphnia was 0.0048 mg/l,  $EC_{50} > 0.0048$  mg/l and for algae NOEC was 0.011 mg/l and  $EC_{50} > 0.011$ mg/l (read across to EHMC). The results show that the substance is potentially T.

It is proposed to investigate further the PBT properties and the reasoning and the applicability of the used read across. The substance is poorly water soluble (0.000872 mg/L). Therefore, short-term studies have been waived and long-term studies have been conducted on the surrogate material. Sediment toxicity testing on the substance could be considered. Also the use pattern and the fate and behaviour of the substance in the environment could be investigated under substance evaluation.

#### 4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	

#### 4.5 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 type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

Further testing, e.g. biodegradation studies /sediment toxicity studies on the substance, might be needed depending on the outcome of the substance evaluation.

Clarification on the use in consumer products.

#### 4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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The follow-up measures depend on the outcome of the substance evaluation.