Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Climbazole
Chemical Group:	Organic
EC Number:	253-775-4
CAS Number:	38083-17-9
Submitted by:	UK CA
Published:	20/03/2013

NOTE

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

Contents

1 IDENTITY OF THE SUBSTANCE

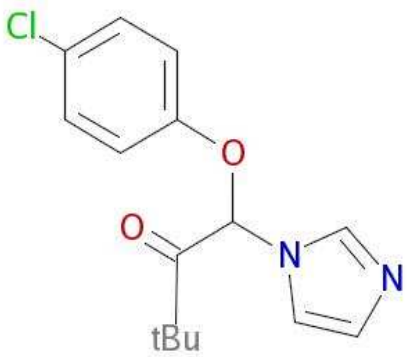
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Climbazole
EC number:	253-775-4
EC name:	climbazole
CAS number (in the EC inventory):	38083-17-9
CAS number:	38083-17-9
CAS name:	2-Butanone, 1-(4-chlorophenoxy)-1-(1H-imidazol-1-yl)-3,3-dimethyl-
IUPAC name:	1-(4-chlorophenoxy)-1-(1H-imidazol-1-yl)-3,3-dimethylbutane-2-one
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula:	$C_{15}H_{17}ClN_2O_2$
Molecular weight or molecular weight range:	293
Synonyms:	Trade names:, Crinipan® USP, Crinipan® AD, CLIMBAZOLE CRUDE

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not applicable

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

2.3 Self classification

By the registrant (from the dissemination site);

CLP:

Acute Tox 4; H302: Harmful if swallowed.

Aquatic Acute 1; H400: Very toxic to aquatic life

Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.

DSD:

Xn; R22 Harmful if swallowed.

N; R50/53 Dangerous for the environment; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Notified classification and labelling according to CLP criteria

The classification and labelling inventory additionally include the following classifications.

Acute Tox. 3; H301: Toxic if swallowed.

Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☐ Article 44(1) (refined prioritisation criteria for substance evaluation)

☒ Article 45(5) (Member State priority)

3.2 Grounds for concern

☒ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☒ Consumer use	☐ High RCR
☐ (Suspected) PBT	☐ Exposure of sensitive populations	☐ Aggregated tonnage
☐ Suspected endocrine disruptor	☒ Other (provide further details below)	

Climbazole is used in cosmetics. There is potential concern for developmental toxicity based on the findings in the existing developmental toxicity studies. In order to assess whether climbazole causes developmental toxicity, more information on the extent of the effects observed in the foetuses, and the severity of the maternal toxicity, is required.

In addition, the maternal toxicity reported included self-mutilation. Further information may be required to determine the cause of these effects.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☒ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	
☐ 100,000 – 1000,000 tpa	☐ > 1000,000 tpa	
☐ Confidential		

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

Industrial Uses:
Manufacture of cosmetic products
ECETOC TRA scenario "Formulators"

Professional Uses:
Professional use of cosmetic products

Consumer Uses:
End use of cosmetic products

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

☐ Compliance check final decision	☐ Dangerous substances Directive 67/548/EEC
☒ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC
☐ Annex XIV (Authorisation)	☒ Other (provide further details below)
☐ Annex XVII (Restriction)	

Climbazole is currently regulated in the Cosmetics Directive as a preservative in Annex VI, entry 32, with a maximum authorized concentration of 0.5%. There are SCCP scientific opinions available regarding the consumer uses.

Testing proposals made:
- Dissociation constant: OECD 112
- Toxicity terrestrial plants: OECD 208

3.5 Information to be requested to clarify the suspected risk

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Other (provide further details below)	

Information to clarify the cause of the maternal toxicity observed in the reproductive toxicity studies may be required.

3.6 Potential follow-up and link to risk management

☐ Restriction	☒ Harmonised C&L	☐ Authorisation	☐ Other (provide further details)

Depending on the outcome of the evaluation, a harmonised classification and labeling proposal may be necessary.