Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	1,1'-iminodipropan-2-ol
Chemical Group:	primary alcohol with secondary amine
EC Number:	203-820-9
CAS Number:	110-97-4
Submitted by:	Czech Republic
Published:	20/03/2013

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1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	1,1'-iminodipropan-2-ol
EC number:	203-820-9
EC name:	1,1'-iminodipropan-2-ol
CAS number (in the EC inventory):	-
CAS number:	110-97-4
CAS name:	2-Propanol, 1,1'-iminobis-
IUPAC name:	1,1'-iminodipropan-2-ol
Index number in Annex VI of the CLP Regulation	603-083-00-7
Molecular formula:	C6H15NO2
Molecular weight or molecular weight range:	133.1888
Synonyms:	2-Propanol, 1,1'-iminobis- 1,1'-iminodipropan-2-ol 1,1'-Iminobis[2-propanol] 2-Propanol, 1,1'-iminobis- (9CI) 2-Propanol, 1,1'-iminodi- (6CI, 7CI, 8CI) Bis(2-hydroxypropyl)amine Bis(2-propanol)amine Diisopropanolamine DIPA DIPA (alcohol) N,N-Bis(2-hydroxypropyl)amine

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

Structural formula:

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

CLP: Eye Irrit. 2; H319: Cause serious eye irritation.

DSD: Xi; R36: Irritating to eyes.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

Notified classification and labeling

The registrations and most of the notifications to the Classification and labelling inventory are consistent with the harmonised classification. In addition the following classification is notified:

Eye Dam. 1; H318: Causes serious eye damage.

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)	

The substance is classified as Eye Irrit. 2 but some notifications give self classification as Eye Dam. 1. It is not classified for skin irritation or sensitization. However individual cases of contact sensitisation in response to DIPA exposure have been reported in human studies. In a human study, in which 24 volunteers received undiluted DIPA to the skin, dermal irritation was observed in six individuals.
There is high worker exposure and high RCR were identified for dermal and Long-term exposure, systemic, combined RCR.

Bis(2-hydroxypropyl)-amine (DHPA) alone induced no foci, but putative pre-neoplastic GST-P-positive foci were observed in the liver and increased dose-dependently in rats which had received DHPA and NaNO2. The results indicate that endogenously synthesized NDHPA from DHPA and NaNO2 is capable of initiating neoplastic development in the rat liver.

Finally, the 2 gen study was waived and 3 studies (an OECD Test Guideline 422, and two one-generation studies according to U.S. FDA Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food - 21 CFR 314.50(d)(2)) using read-across were given to cover the endpoint requirement. Therefore no data on the substance are available for fertility endpoint.

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	☒ 1,000+ tpa
☐ Confidential		

Reported as 1000 + tonnes per annum on the ECHA dissemination site.

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

Some relevant uses: Use in detergents and cleaners, and personal care products.

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

☐ Compliance check	☐ 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)	
Please provide further details	

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)	
Due to wide dispersive use including consumer use (such as use in detergents and cleaners and personal care products), observed dermal toxicity in humans (not included in classification), potential to initiate neoplastic development in the rat liver in the presence of NaNO2 and lack of data for fertility toxicity, the substance might merit to be evaluated.	

3.6 Potential follow-up and link to risk management

☒ Restriction	☒ Harmonised C&L	☐ Authorisation	☐ Other (provide further details)
The new data might bring an update for dermal toxicity classification and their possible restriction in several consumer products.			