Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Propyl Acetate
Chemical Group:	
EC Number:	203-686-1
CAS Number:	109-60-4
Submitted by:	Ireland
Date:	17/03/2015

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

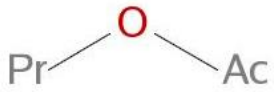
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Propyl acetate
IUPAC name:	Propyl acetate
Index number in Annex VI of the CLP Regulation	607-024-00-6
Molecular formula:	C5H10O2
Molecular weight or molecular weight range:	102.1317
Synonyms/Trade names:	Acetic acid, propyl ester

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

Structural formula:



1.2 Similar substances/grouping possibilities

Propyl acetate is grouped in Annex VI of CLP with isopropyl acetate (EC No. 203-561-1). The OECD HPV SIDS assessment includes data for two analogue substances ethyl acetate (EC No. 205-500-4) and n-butyl acetate (EC No. 204-658-1). Details can be found at the following link: http://webnet.oecd.org/hpv/ui/handler.axd?id=bf44bca4-ef10-46fc-8163-1737f208f063

Structural formulae:

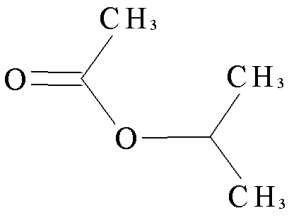


Fig. 1 Isopropyl acetate

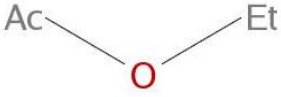


Fig. 2 Ethyl Acetate

Fig. 3 n-Butyl Acetate

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Table 2: 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)		
607-024-00-6	propyl acetate; [1] isopropyl acetate [2]	203-686-1 [1] 203-561-1 [2]	109-60-4 [1] 108-21-4 [2]	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3	H225 H319 H336		

2.2 Self classification

- The registration dossiers have applied the harmonized classification in Annex VI of CLP.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - STOT SE 1; H370: Causes damage to organs
  - Flam. Liq. 1; H224: Extremely flammable liquid and vapour

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☒ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

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

Propyl acetate is manufactured in the EU. It is a solvent used in coatings (paints, inks and adhesives), cleaning agents and lubricants for industrial, professional and consumer uses. It is also used in metal working and rolling oils and as a laboratory reagent by industrial and professional users, and in consumer care products and disinfectants.

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 ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☒ Other (provide further details below)
☐ Annex XVII (Restriction)	

The registered substance was evaluated under the OECD HPV program (SIAM 27), please see http://webnet.oecd.org/hpv/ui/handler.axd?id=bf44bca4-ef10-46fc-8163-1737f208f063.

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

☒ 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 ☐C ☐M ☐R	Suspected CMR[1] ☐C ☐M ☒R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[1]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☒ Other (please specify below)
Exposure/risk based concerns		
☒ Wide dispersive use	☒ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☒ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☒ High (aggregated) tonnage	☐ Other (please specify below)

[1] 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

The identified uses in the registration dossiers indicate the potential for dermal and inhalation exposure to both workers and consumers. Further review of the exposure assessment and the adequacy of the existing risk management measures in the registration dossiers are required. In addition, the robustness of the DNELs and the corresponding RCRs relating to both short and long term human exposure should also be assessed.

There are no developmental toxicity studies reported in the registration data for propyl acetate. The registration data includes studies for the read-across substances propan-1-ol and n-butyl acetate. In a pre-natal developmental toxicity study, two groups of rats were exposed to n-butyl acetate by inhalation, one group for days 7-19 of gestation and the other for days 1-19 of gestation. Increased incidence of rib dysmorphology and reduced pelvic ossification were observed. Two minor anomalies, misaligned sternebrae and retinal folds, were observed in an identical study with rabbits. In a pre-natal developmental toxicity study in rats with propan-1-ol a significant reduction in body weight and incidence of live implants/litter, and a significant increase of external, skeletal and visceral malformations and resorptions was observed, when compared to controls.

There are no reproductive toxicity data reported in the registration data for propyl acetate, however a two generation reproductive toxicity study (OECD 416) and one generation study (non-guideline) are available for the read-across substances n-butyl acetate and propan-1-ol, respectively. Following inhalation exposure to n-butyl acetate, no adverse effects on reproductive capability were reported in the two generation study. In the one generation study with propan-1-ol administered by the inhalation route, a significant reduction of the number of males that successfully mated was observed, however a subgroup of these males were kept for a 13 week recovery period following the study, and all of the subgroup demonstrated a recovery of fertility.

Based on this information and in agreement with the conclusions of the SIDS evaluation (OECD HPV program), there is potential concern for reproductive and developmental toxicity which requires further evaluation.

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

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

Following evaluation of the existing data, additional developmental and/or reproductive toxicity data may be required.

Further information on the use and/or exposure may be required to clarify the potential exposure to workers and consumers. Verification of the robustness of the risk characterisation and the adequacy of the existing risk management measures may also be requested.

5.5 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Follow up actions are not readily identifiable at this stage and will be considered once the hazard, exposure and risk characterisation information have been evaluated.			