Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	[1,3(or 1,4)-phenylenebis(1-methylethylidene)] bis[tert-butyl] peroxide
Chemical Group:	
EC Number:	246-678-3
CAS Number:	25155-25-3
Submitted by:	NL-CA
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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 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	[1,3(or 1,4)-phenylenebis(1-methylethylidene)] bis[tert-butyl] peroxide
EC number:	246-678-3
EC name:	[1,3(or 1,4)-phenylenebis(1-methylethylidene)] bis[tert-butyl] peroxide
CAS number (in the EC inventory):	25155-25-3
CAS number:	25155-25-3
CAS name:	
IUPAC name:	Reaction mass of 1,3-bis[2-(terbutylperoxy) propan-2-yl]benzene and 1,4-bis[2-(terbutylperoxy)propan-2-yl]benzene
Index number in Annex VI of the CLP Regulation	Not applicable.
Molecular formula:	$C_{20}H_{34}O_4$
Molecular weight or molecular weight range:	ca. 338,5
Synonyms/Trade names:	Perkadox 14 Perkadox 14-40 Perkadox 14-55

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

Structural formula:

N.A.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

No data

2.3 Self classification

According to CLP criteria:

- Org. Perox. Type D; H242: Heating may cause a fire.
- Aquatic Chronic 4 H413: May cause long lasting harmful effects to aquatic life.

According to DSD criteria:

- O; R7 Oxidising; May cause fire.
- R53 May cause long-term adverse effects in the aquatic environment.

The following additional classifications have been notified to the Classification and Labelling Inventory:

- Org. Perox. Type B; H241: Heating may cause a fire or explosion.
- Skin Irrit. 2; H315: Causes skin irritation.
- Eye Irrit. 2; H319: Causes serious eye irritation.

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/vPvB	☐ Exposure of sensitive populations	☒ Aggregated tonnage
☐ Suspected endocrine disruptor	☐ Other (provide further details below)	
It should be noted that a CSR is not available for this substance. The screening criterion for P (0% degradation in ready biodegradation test) is met, however no test data are available to assess the ultimate criteria for persistence. The B screening criterion (log Kow exp. > 5,5) is met, but no experimental BCF-data are available. The substance is not T: short term toxicity studies do not show toxicity up to water solubility levels. Ultimate criteria (aquatic chronic toxicity) still have to be tested. Although these triggers would suggest further testing to confirm or deny the PBT/vPvB properties, adequate data are lacking. The substance is used in professional wide dispersive use both indoor & outdoor, indicating potential for dispersion into the environment.		

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
In addition, the professional use is characterised as being wide-dispersive.			

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

☐ Compliance check final	☐ 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)	

There is testing proposal for the following end point;

- 90-day oral toxicity study (OECD 408) in rats, oral route
- Developmental toxicity / teratogenicity study (OECD 414)
- Toxicity to aquatic invertebrates: Daphnia magna reproduction test (OECD 211)
- Sediment toxicity: Sediment-water Chironomid toxicity using spiked sediment (OECD 218)

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 on fate and behaviour and (eco)toxicology would be requested. More information about the biodegradation of the substance would make it possible to draw a definitive conclusion for the P status. When ultimate criteria for P are fulfilled, also the bioaccumulative properties of the substances should be further tested and when needed long-term aquatic toxicity tests should be required.

3.6 Potential follow-up and link to risk management

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

A potential follow-up regulatory action would be authorisation of the substance, if the substance turns out to be PBT.