CLH report

Proposal for Harmonised Classification and Labelling

**Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2**

Chemical name: Dibenzoyl peroxide; benzoyl peroxide

EC Number: **202-327-6**

CAS Number: **94-36-0**

Index Number: **617-008-00-0**

Contact details for dossier submitter:

Health and Safety Authority,

The Metropolitan Building,

James Joyce Street,

Dublin 1, D01 K0Y8,

Ireland.

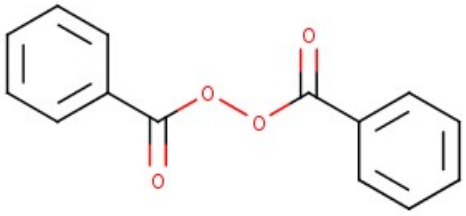
Version number: 2.0 **Date: 23/11/2021**

CONTENTS

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)	Dibenzoyl peroxide; benzoyl peroxide
Other names (usual name, trade name, abbreviation)	Benzoyl peroxide; Diphenylperoxyanhydride; Methanone, 1,1'-dioxybis[1-phenyl-; Benzoic acid, peroxide; Benzoperoxide; Benzoyl superoxide;
ISO common name (if available and appropriate)	Not applicable
EC number (if available and appropriate)	202-327-6
EC name (if available and appropriate)	Dibenzoyl peroxide
CAS number (if available)	94-36-0
Other identity code (if available)	617-008-00-0
Molecular formula	$C_{14}H_{10}O_4$
Structural formula	
SMILES notation (if available)	O=C(OOC(=O)C1=CC=CC=C1)C1=CC=CC=C1
Molecular weight or molecular weight range	242.227g
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	Not applicable
Description of the manufacturing process and identity of the source (for UVCB substances only)	Not applicable
Degree of purity (%) (if relevant for the entry in Annex VI)	>=73.5 - <=76.5 % (w/w)

1.2 Composition of the substance

Table 2: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum in multi-constituent substances)	Current CLH in Annex VI Table 3 (CLP)	Current self- classification and labelling (CLP)
Dibenzoyl peroxide EC No. 202-327-6 CAS No. 94-36-0	Mono-constituent substance	Org. Perox. B H241 Eye Irrit. 2 H319 Skin Sens. 1 H317	Org. Perox. B H241 Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Acute 1 H400 (M factor=10) Aquatic Chronic 1 H410 (M factor=10)

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3 (CLP)	Current self-classification and labelling (CLP)	The impurity contributes to the classification and labelling

No impurities relevant for classification.

Table 4: Additives (non-confidential information) if relevant for the classification of the substance

Additive (Name and numerical identifier)	Function	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3 (CLP)	Current self-classification and labelling (CLP)	The additive contributes to the classification and labelling

No additives relevant for classification.

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 5: Proposed harmonised classification and labelling according to the CLP criteria

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	617-008-00-0	Dibenzoyl peroxide; benzoyl peroxide	202-327-6	94-36-0	Org. Perox. B Eye Irrit. 2 Skin Sens. 1	H241 H319 H317	GHS02 GHS01 GHS07 Dgr	H241 H319 H317	-	-	-
Dossier submitters proposal					**Add** Aquatic Acute 1 Aquatic Chronic 1	**Add** H400 H410	**Add** GHS09	**Add** H410	-	**Add** M=10 M=10	-
Resulting Annex VI entry if agreed by RAC and COM					Org. Perox. B Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H241 H319 H317 H400 H410	GHS02 GHS01 GHS07 GHS09 Dgr	H241 H319 H317 H410	-	M=10 M=10	-

Table 6: Reason for not proposing harmonised classification and status under consultation

Hazard class	Reason for no classification	Within the scope of consultation
Explosives	Hazard class not assessed in this dossier	No
Flammable gases (including chemically unstable gases)		
Oxidising gases		
Gases under pressure		
Flammable liquids		
Flammable solids		
Self-reactive substances		
Pyrophoric liquids		
Pyrophoric solids		
Self-heating substances		
Substances which in contact with water emit flammable gases		
Oxidising liquids		
Oxidising solids		
Organic peroxides		
Corrosive to metals		
Acute toxicity via oral route		
Acute toxicity via dermal route		
Acute toxicity via inhalation route		
Skin corrosion/irritation		
Serious eye damage/eye irritation		
Respiratory sensitisation		
Skin sensitisation		
Germ cell mutagenicity		
Carcinogenicity		
Reproductive toxicity		
Specific target organ toxicity-single exposure		
Specific target organ toxicity-repeated exposure		
Aspiration hazard		
Hazardous to the aquatic environment	Harmonised classification proposed: Aquatic Acute 1 (M factor=10) Aquatic Chronic 1 (M factor=10)	Yes
Hazardous to the ozone layer	Hazard class not assessed in this dossier	No

3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

Dibenzoyl peroxide was classified under the Dangerous Substance Directive (DSD) 67/548/EEC for physical (R3 and R7) and human health hazards (R36 and R43) and included in Annex I of the DSD in accordance with the 30th Adaptation to Technical Progress (ATP) (Commission Directive 2008/58/EC). The harmonised classification was translated to the CLP Regulation (EC) No. 1272/2008, as Organic Peroxide B H241, Eye Irritant Category 2 H319, and Skin Sensitisation Category 1 H317, and included in Annex VI Table 3.2 of the CLP Regulation (EC) No. 1272/2008 by the 1st ATP (Commission Regulation (EC) No 790/2009).

The current entry in Annex VI of CLP of dibenzoyl peroxide does not include harmonised classification for environmental hazards (i.e. hazardous to the aquatic environment). This proposal intends to update the current harmonised classification entry by including Aquatic Acute Category 1 (M factor=10) and Aquatic Chronic Category 1 (M factor=10).

4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Justification that action is needed at Community level is required.

Reason for a need for action at Community level:

Change in existing entry due to new data for environmental endpoints
Differences in self-classification among the C&L Inventory notifiers with respect to classification for environmental hazards (1701 notifiers and 26 aggregated notifications).

5 IDENTIFIED USES

According to the REACH Registration dossier (ECHA, 2021a), dibenzoyl peroxide is an organic peroxide in the form of a granular powder (crystal) and is used in polymerisation reactions (polymers, resins, rubbers) and as an intermediate, adhesive, sealant, coating resin hardener, and toner by industrial and professional workers. It is also formulated into fillers, adhesives, sealants, cosmetics and personal care products for use by consumers (ECHA, 2021a).

6 DATA SOURCES

Data for dibenzoyl peroxide is taken from:

- Publically disseminated REACH registration dossier (ECHA, 2021a).
- Publically available literature.

7 PHYSICOCHEMICAL PROPERTIES

Table 7: Summary of physicochemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
Physical state at 20°C and 101,3 kPa	Solid (white crystalline powder)	ECHA, 2021a	Measured
Melting/freezing point	106°C at 101.3 kPa	ECHA, 2021a	Available literature
Boiling point	No data	ECHA, 2021a	The registration dossier provided an adaptation in accordance with column 2 of Annex VII of REACH.
Relative density	1.33 at 25°C	ECHA, 2021a	Measured
Vapour pressure	0.009 Pa at 25°C	ECHA, 2021a	Estimated
Surface tension	No data	ECHA, 2021a	The registration dossier provided an adaptation in accordance with column 2 of Annex VII of REACH.
Water solubility	0.35 mg/L at 20ºC	ECHA, 2021a	Measured Note: dibenzoyl peroxide undergoes rapid abiotic degradation. Benzoic acid is the main degradation product and has a water solubility of 2.9 g/L at 20ºC.
Partition coefficient n-octanol/water	Log Kow: 3.2 at 22°C	ECHA, 2021a	Measured
Flash point	Not applicable	ECHA, 2021a	The registration dossier provided an adaptation in accordance with column 2 of Annex VII of REACH.
Flammability	No data	ECHA, 2021a	The registration dossier provided an adaptation in accordance with column 2 of Annex VII of REACH.
Explosive properties	Explosive	ECHA, 2021a	Dibenzoyl peroxide is classified as Organic Peroxide Type B (reference CLP regulations 2.15.1.2, 2.15.2.2 and UN Recommendations on the Transport of Dangerous Goods, 16th revised edition, section 2.5.3.2.4).
Self-ignition temperature	No data	ECHA, 2021a	The registration dossier provided an adaptation in accordance with column 2 of Annex VII of REACH.

Property	Value	Reference	Comment (e.g. measured or estimated)
Oxidising properties	No data	ECHA, 2021a	The registration dossier provided an adaptation in accordance with column 2 of Annex VII of REACH.
Granulometry	135µm (wet powder)	ECHA, 2021a	Measured as a wet powder.
Stability in organic solvents and identity of relevant degradation products	Not applicable	ECHA, 2021a	Only required if the stability of the substance is considered critical.
Dissociation constant	No data	ECHA, 2021a	The registration dossier provided an adaptation in accordance with section 1 of Annex XI of REACH.
Viscosity	No data	ECHA, 2021a	The registration dossier provided an adaptation in accordance with section 1 of Annex XI of REACH.

8 EVALUATION OF PHYSICAL HAZARDS

Not evaluated as part of this dossier.

9 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Not evaluated as part of this dossier.

10 EVALUATION OF HEALTH HAZARDS

Not evaluated as part of this dossier.

11 EVALUATION OF ENVIRONMENTAL HAZARDS

11.1 Rapid degradability of organic substances

Table 8: Summary of relevant information on rapid degradability

Method	Test Material	Results	Remarks	Reference
OECD 301 D (Ready Biodegradability: Closed Bottle Test)	Dibenzoyl peroxide Purity: 74.3%	Readily biodegradable. 71% degradation of test substance after 28 days (% degradation (O_2 consumption)). 10-day window pass level requirement achieved.	Key study. Reliability score 1 (reliable without restriction). GLP compliant. No deviations.	Anonymous, 2015b. ECHA Dissemination site, 2021.

Method	Test Material	Results	Remarks	Reference
OECD 301 D (Ready Biodegradability: Closed Bottle Test)	Dibenzoyl peroxide Purity: 74.6%	Inherently biodegradable. 68% degradation of test substance after 28 days (% degradation (O_2 consumption)). 10-day window pass level requirement not achieved.	Supporting study. Reliability score 2 (reliable with restriction). GLP compliant. The inoculum cell density (10^7 to 10^8 cells/litre) was higher than recommended by the OECD 301 Test Guideline (10^4 to 10^6 cells/litre).	Anonymous, 2009c. ECHA Dissemination site, 2021.
OECD 301 D (Ready Biodegradability: Closed Bottle Test)	Dibenzoyl peroxide Purity: 74.4%	Not readily biodegradable. 56% degradation of test substance after 28 days (% degradation (O_2 consumption)).	Supporting study. Reliability score 2 (reliable with restriction). Deviations from the test guideline are reported. It is unclear if these deviations affected the biodegradation potential of the test material or validity of the study. Refer to Section 11.1.1 and Annex I of the CLH report for further study details. GLP compliant.	Anonymous, 1990. ECHA Dissemination site, 2021.
OECD 301 C (Ready Biodegradability: Modified MITI Test (I))	Dibenzoyl peroxide Purity: information not available	Readily biodegradable. 88% degradation of the test substance after 21 days (% degradation (TOC removal)).	Not enough data available to evaluate the validity of the study. Reliability score 4 (not assignable).	Anonymous, 1992. ECHA Dissemination site, 2021.

11.1.1 Ready biodegradability

The ready biodegradability of dibenzoyl peroxide was evaluated in four ready biodegradability studies in accordance with international standards or accepted guidelines. The reliability scores assigned to the studies range between 1 and 4 (Klimisch H.J., Andreae M., and Tillmann U, 1997).

The ready biodegradability of dibenzoyl peroxide was evaluated in a valid GLP compliant OECD Ready Biodegradability closed bottle test (OECD 301 D) (Anonymous, 2015b). Secondary activated sludge (non-adapted, 0.4 g (DW)/L pre-conditioned), obtained from the Nieuwgraaf wastewater treatment plant in Duiven (The Netherlands), was exposed to 2 mg/L dibenzoyl peroxide for 28 days. The test temperature reportedly ranged between 22-24°C. Under the test conditions, dibenzoyl peroxide reported a theoretical oxygen demand (ThOD) of 2.7 mg/L, corresponding to 71% degradation after 28 days. The 10-day window pass level was achieved with over 60% biodegradation reported in a period of approximately 10 days immediately following the attainment of 10% biodegradation. The dossier submitter considers the validity criteria of the test, as stipulated in the OECD 301 guideline, fulfilled. The reference substance, sodium acetate, reached 91% degradation after 14 days and 1.2 mg/L endogenous respiration at Day 28. The residual oxygen concentration remained above 0.5 mg/L in all test bottles over the duration of the test. The dossier submitter considers that under the conditions of the study, dibenzoyl peroxide can be considered readily biodegradable.

In a second GLP OECD 301 D (Anonymous, 2009c) test, activated sludge (concentration equivalent to a maximum of 30 mg/L, pre-conditioned, non-adapted), prepared in the laboratory from secondary effluent from a wastewater treatment plant with activated sludge treating domestic wastewater in the municipality of Abidos (France), was exposed to 4 mg/L dibenzoyl peroxide for 28 days. The oxygen depletion in the inoculum blank did not exceed 1.5 mg/L after 28 days. However, the residual oxygen concentration remained above 0.5 mg/L. The reference substance, sodium benzoate, reached 42% degradation by Day 14 which is below the validity threshold of ≥ 60%. The validity criteria of the test, as stipulated in the OECD 301 guideline, were not fulfilled. Under the conditions of the study, dibenzoyl peroxide biodegraded 68% by Day 28, exceeding the 60% threshold for this test system. However, this level of biodegradation was not achieved within the 10-day window. The dossier submitter considers that, under the conditions of the study, dibenzoyl peroxide demonstrated inherent biodegradability.

In a further GLP compliant OECD 301 D (Anonymous, 1990) test, the ready biodegradability of dibenzoyl peroxide, 1.5 mg/L (applied using silica gel), was investigated in secondary activated sludge (non-adapted, pre-conditioned) from an activated sludge plant predominantly treating domestic wastewater in Duiven, The Netherlands. After 28 days, dibenzoyl peroxide reportedly degraded by 56%. The test was extended to 84 days, however, the level of degradation did not exceed 56%. The reference substance, sodium acetate, biodegraded by 88 and 94 % by Day 15 and 28, respectively. The study summary reports that inhibitory effects of dibenzoyl peroxide on the micro-organisms of the inoculum were not observed. Considering the extent of degradation, the dossier submitters considers that dibenzoyl peroxide did not fulfil the ready biodegradability criteria. Under the conditions of the study, it was concluded that dibenzoyl peroxide can be considered as not readily biodegradable. The dossier submitter notes that although the validity criteria of the OECD 301 guideline were fulfilled the following deviations were noted (please see Annex I for further study details): secondary activated sludge was used as the inoculum instead of the recommended secondary

effluent (or surface water) as per the OECD 301 guideline. The OECD 301 D guideline recommends for substances with a water solubility below 1 g/L that stock solutions are prepared in mineral medium or added directly to the mineral medium rather than in water/solvent as was performed in the study. A test concentration of 1.5 mg/L dibenzoyl peroxide was used in the study. In accordance with the general test conditions reported in Table 2 of the OECD 301 guideline, a test concentration of between 2-10 mg/L is recommended for the OECD 301 D test system.

The ready bioavailability of dibenzoyl peroxide was evaluated in accordance with an OECD Ready Biodegradability modified MITI test (OECD 301 C) (Anonymous, 1992) for 21 days. Under the conditions of the study, dibenzoyl peroxide reported 88% degradation after 21 days. The robust study summary concluded that dibenzoyl peroxide was readily biodegradable, however, no further information is reported in the study summary for the dossier submitter to verify the validity of the study. The study is not considered reliable by the dossier submitter.

The dossier submitter notes that benzoic acid (EC No. 200-618-2) is considered the main degradation product of dibenzoyl peroxide. The robust study summary for benzoic acid, as per the REACH registration dossier, reports that benzoic acid can be considered as readily biodegradable (ECHA dissemination site, 2021b).

11.1.2 BOD_5/COD

No relevant information available.

11.1.3 Hydrolysis

Table 9: Summary of relevant information on hydrolysis

Method	Test Material	Results	Remarks	Reference
OECD 111	Dibenzoyl peroxide Purity: 74.6%	Dibenzoyl peroxide was determined to be hydrolytically unstable at pH 4, 7 and 9 at 50°C. Half-life (DT_{50}): $T_{1/2}$ (pH 4): <1 day at 25°C; $T_{1/2}$ (pH 7): <1 day at 25°C; $T_{1/2}$ (pH 9): <1 day at 25°C. Degradation product: benzoic acid.	Key study. GLP compliant. Reliability score 1 (reliable without restriction).	Anonymous, 2010d. ECHA Dissemination site, 2021.
OECD 111	Dibenzoyl peroxide Purity: 70%	Half-life (DT_{50}): $T_{1/2}$ (pH 4): 11.9 hr at 25°C; Type: (pseudo-) first order (half-life) $T_{1/2}$ (pH 7): 5.2 hr at 25°C;	Supporting information. Non-GLP. Not enough data available to	Anonymous, 2001c. ECHA Dissemination site, 2021.

Method	Test Material	Results	Remarks	Reference
		Type: (pseudo-)first order (half-life) $T_{1/2}$ (pH 9): not detected.	evaluate the validity of the study. Reliability score 4 (not assignable).	

In a GLP compliant OECD Hydrolysis as a Function of pH (OECD 111) study (Anonymous, 2010d), dibenzoyl peroxide was determined to be hydrolytically unstable at acidic (pH 4), neutral (pH 7) and alkaline (pH 9) conditions at 50°C. The rate of hydrolysis increased with increasing pH and resulted in the availability of approximately 20% of the applied test substance to measure at pH 9 on initial sampling. The corresponding first order hydrolysis rate constant was determined. The robust study summary reports that greater than 50% hydrolysis occurred after 2.4 hours, equivalent to a half-life (DT_{50}) of less than 1 day under environmentally relevant condition (25°C). Hydrolysed samples were analysed at each test pH under modified HPLC conditions. The principal hydrolysis product, benzoic acid, was detected in the hydrolysed solutions that were sampled at each tested pH. The dossier submitter notes that the available data for benzoic acid, as reported in the REACH registration dossier (ECHA, 2021b), suggests that benzoic acid can be considered as readily biodegradable and has a low bioaccumulation potential (log Kow < 2). Benzoic acid has a harmonised classification as Skin Irritant 2, Eye Damage 1, and STOT RE 1 (Index number 607-705-00-8). Benzoic acid does not have a harmonised classification entry for environmental hazards.

The hydrolytic stability of non-radiolabelled dibenzoyl peroxide was investigated in a preliminary non-GLP compliant study in accordance with OECD 111 (Anonymous, 2001c). The robust study summary indicates that, under the conditions of the study, dibenzoyl peroxide degraded 93.5, 94.1 and 94.2% by Day 5 at pH 4, 7 and 9 and at 50 ºC, respectively. The half-life of dibenzoyl peroxide at pH 4 and 7 was determined to be 11.9 hours and 5.2 hours at 25°C, respectively, while the half-life at pH 9, at 25°C, could not be determined as dibenzoyl peroxide was not detected. However, no further information is reported in the robust study summary for the dossier submitter to verify the validity of the study or the observed results. The study is not considered reliable by the dossier submitter.

Based on the available information, the dossier submitter considers dibenzoyl to be hydrolytically unstable at pH 4, 7 and 9. The DT_{50} (25°C) is estimated to be < 1 day. The robust study summary indicates that no additional testing was performed.

11.1.4 Other convincing scientific evidence

Using EPISuite (HENRYWIN v3.20), the dossier submitter calculated a Henry's Law constant of dibenzoyl peroxide of 3.54 x 10^{-6} Pa m³/mol, suggesting little potential for dibenzoyl peroxide to volatilise in the environment. The registration dossier reports that dibenzoyl peroxide has a vapour pressure of 9 x 10^{-3} Pa at

25°C and can be considered as non-volatile. Substances with a Henry Law constant below 3.04 x 10^{-2} Pa m³/mol are less volatile than water and can be considered essentially non-volatile.

11.1.4.1 Field investigations and monitoring data (if relevant for C&L)

Not relevant.

11.1.4.2 Inherent and enhanced ready biodegradability tests

No data available or required. Please refer to section 11.1.1.

11.1.4.3 Water, water-sediment and soil degradation data (including simulation studies)

No data available.

11.1.4.4 Photochemical degradation

An atmospheric half-life of 3.009 days for dibenzoyl peroxide was calculated, by the dossier submitter, using EPISuite (AOPWIN v1.92).

11.1.5 Summary and discussion on environmental degradation.

Abiotic degradation: Dibenzoyl peroxide was determined to be hydrolytically unstable at pH 4, 7 and 9 with an estimated DT_{50} (25°C) of < 1 day. In addition, dibenzoyl peroxide has a Henry Law constant value (calculated) of 3.54 x 10^{-6} Pa m³/mol and is considered to be non-volatile.

Biotic degradation: the readily biodegradability of dibenzoyl peroxide was tested in accordance with three OECD 301D and one OECD 301C ready biodegradability studies. The rate of degradation ranged from between 56 to 88%. In accordance with Annex I: 4.1.2.9.5 of the CLP Regulation (EC) No. 1272/2008, *'Substances are considered rapidly degradable in the environment if one of the following criteria holds true (a) if, in 28-day ready biodegradation studies, at least the following levels of degradation are achieved: (i) tests based on dissolved organic carbon: 70 %; (ii) tests based on oxygen depletion or carbon dioxide generation: 60 % of theoretical maximum.'*. In conclusion, based upon the available information (as presented in Table 11 and section 11.1.1), the dossier submitter considers dibenzoyl peroxide to be rapidly degradable in the environment.

11.2 Environmental transformation of metals or inorganic metals compounds

Not relevant.

11.3 Environmental fate and other relevant information

No further data.

11.4 Bioaccumulation

Table 10: Summary of relevant information on bioaccumulation

Method	Results	Remarks	Reference
EPISuite KOWWIN and BCFBAF	log Kow 3.43 BCF = 89.11 L/kg	-	EPISuite, 2021.
OECD 121	log Koc 3.8 at 22°C Purity: 74.6%	Key study. GLP compliant. No deviations. Reliability score of 1 (reliable without restriction).	Anonymous, 2009a. ECHA dissemination site, 2021.
OECD 117	log Kow 3.2 at 22°C Purity: 74.6%	Key study. GLP compliant. No deviations. Reliability score of 1 (reliable without restriction).	Anonymous, 2009b. ECHA dissemination site, 2021.

11.4.1 Estimated bioaccumulation

The EPISuite KOWWIN (v1.68) and BCFBAF QSAR models predict a log Kow and BCF value for dibenzoyl peroxide of 3.43 (log Kow 3.43) and 89.11 L/kg, respectively.

11.4.2 Measured partition coefficient and bioaccumulation test data

The partition coefficient of dibenzoyl peroxide was determined experimentally in a GLP compliant OECD Partition Coefficient (n-octanol) study (OECD 117) which reported a partition coefficient value of 3.2 (log Kow 3.2) at 22°C (Anonymous, 2009a). Aquatic bioaccumulation studies to determine the bioconcentration of dibenzoyl peroxide in aquatic species are not available.

The adsorption/desorption behaviour of dibenzoyl peroxide on soil and sewage sludge was evaluated in a GLP compliant OECD Estimation of the Adsorption Coefficient on Soil and on Sewage Sludge study using High Performance Liquid Chromatography (OECD 121) (Anonymous, 2009a). An organic carbon-water partition coefficient value (Koc) of 6310 for dibenzoyl peroxide was reported corresponding to a log Koc of 3.8 at 22°C. As per Section R.7.9.4.3 of ECHA's Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7b, substances with log Koc > 4 are generally regarded as highly adsorptive and likely to distribute in sediment and soil. Dibenzoyl peroxide can be considered moderately-to-highly adsorptive.

According to the CLP Regulation (EC) No. 1272/2008, "*a cut-off value of log Kow ≥ 4 is intended to identify only those substances with a real potential to bioconcentrate…A BCF in fish of ≥ 500 is indicative of the*

potential to bioconcentrate for classification purposes". For classification purposes, the log Kow value is used when an experimentally determined BCF is not available.

As there are no experimental BCF studies reported in the registration dossier, the bioaccumulation potential of dibenzoyl peroxide was determined by comparing the experimentally derived log Kow value with the CLP cut-off criteria. Considering this, dibenzoyl peroxide is considered to have a low bioaccumulation potential based on the experimentally derived log Kow of 3.2, which is less than the CLP cut-off value of ≥ 4. Furthermore, the QSAR calculated log Kow (3.43) and BCF value of dibenzoyl peroxide (89.11 L/kg) are less than the CLP cut-off criteria (log Kow ≥ 4; BCF ≥ 500).

The dossier submitter considers dibenzoyl peroxide to have a low bioconcentration potential and is not considered bioaccumulative for classification purposes.

11.5 Acute aquatic hazard

Table 11: Summary of relevant information on acute aquatic toxicity

Fish					
Method	**Species**	**Test material**	**Results**	**Remarks**	**Reference**
OECD 203; EU Method C.1	*Oncorhynchus mykiss* (Rainbow trout)	Dibenzoyl peroxide Purity: 74.6% Test concentrations (mg/L): Nominal: 0.427, 0.939, 2.07, 4.55 and 10. Mean measured: 0.0081, 0.0097, 0.0224, 0.0316 and 0.0741.	LC_{50} (96 hr, semi-static): 0.0602 mg/L (mean measured)	Key study. GLP compliant. No deviations reported. Reliability score of 1 (reliable without restriction).	Anonymous, 2010a. ECHA dissemination site, 2021.
OECD 203; EU Method C.1	*Poecilia reticulata* (Guppy)	Dibenzoyl peroxide Purity: 74.4% Test concentrations (mg/L): Nominal: 0.7, 1.3, 2.4 and	LC_{50} (96 hr, aerated semi-static): 2 mg/L (nom.)	Supporting study. GLP compliant. Analytical monitoring was not performed. Test organisms	Anonymous, 1989. ECHA dissemination site, 2021.

		4.2.		obtained from local aquarium retailer. The validity criteria of the study are not fulfilled. Reliability score of 3 (not reliable).	
OECD 203; EU Method C.1	*Oryzias latipes* (Japanese medaka)	Dibenzoyl peroxide Purity: 97.3% Test concentrations (mg/L): Nominal: 0.25, 0.5, 1.0, 2.0 and 4. Mean measured: 0.23, 0.47, 0.69, 1.54 and 2.17.	LC_{50} (96 hr, flow-through): 0.24 mg/L (mean measured)	Supporting study. GLP compliant. Source of test species unknown. Length of test species deviated from guideline. The robust study summary indicates the study is of secondary source and the documentation insufficient for assessment. Reliability score of 4 (not assignable).	Anonymous, 2002. ECHA dissemination site, 2021.
OECD 203	*Oryzias latipes* (Japanese medaka)	Dibenzoyl peroxide Purity: Information not available Test concentrations (mg/L): Information not available	LC_{50} (96 hr, static): 3.9 mg/L* *Unknown if the results are based on the nominal or mean measured concentration.	Supporting study. GLP compliant. Not enough information available to evaluate the test design, conditions, and validity.	Anonymous, 1996. ECHA dissemination site, 2021.

				Reliability score of 4 (not assignable).	
Aquatic Invertebrates					
Method	**Species**	**Test material**	**Results**	**Remarks**	**Reference**
OECD 202; EU Method C.2	*Daphnia magna*	Dibenzoyl peroxide Purity: 74.6% Test concentrations (mg/L): Nominal: 0.427, 0.939, 2.07, 4.55 and 10. Mean measured: <LOQ, < LOQ, 0.0416, 0.0765 and 0.157.	EC_{50} (48 hr, static): 0.110 mg/L (mean measured)	Key study. GLP compliant. No deviations reported. Reliability score of 1 (reliable without restriction).	Anonymous, 2010b. ECHA dissemination site, 2021.
OECD (8.1) and EEC (8.2) guidelines	*Daphnia magna*	Dibenzoyl peroxide Purity: 74.4% Test concentrations (mg/L): Water Accommodated Fraction (WAF): negative control, undiluted WAF, 1:2, 1:4, 1:8 and 1:16 WAF dilutions.	EC_{50} (48 hr, static WAF): 2.91 mg/L	Supporting study. GLP compliant. Deviations: test carried out as a WAF with series of dilutions. Insufficient information available to determine if the test substance concentration was maintained throughout the study. Reliability score of 3 (not	Anonymous, 1999a. ECHA dissemination site, 2021.

				reliable).	
OECD 202	*Daphnia magna*	Dibenzoyl peroxide Purity: 79.4% Test concentrations (mg/L): Nominal: 0.03, 0.06, 0.13, 0.25 and 0.5.	EC_{50} (48 hr, static): 0.07 mg/L (nom.)	Supporting study. GLP compliant. The concentration of dibenzoyl peroxide was less than 80% after 1 hr. Insufficient information available to evaluate the test design, conditions, and validity. Reliability score of 4 (not assignable).	Anonymous, 2001a. ECHA dissemination site, 2021.
Aquatic Algae					
Method	**Species**	**Test material**	**Results**	**Remarks**	**Reference**
OECD 201, EU Method C.3	*P.subcapitata*	Dibenzoyl peroxide Purity: 74.6% Test concentrations (mg/L): Nominal: 0.427, 0.939, 2.07, 4.55 and 10. Measured (initial): 0.034, 0.102, 0.166, 0.296, and 0.842 (benzoic acid expressed as dibenzoyl peroxide).	E_rC_{50} (72 hr, static): 0.0711 mg/L (ini. measured) E_bC_{50} (72 hr, static): 0.0422 mg/L (ini. measured) E_yC_{50} (72 hr, static): 0.0724 mg/L (ini. measured)	Key study. GLP compliant. No deviations reported. Reliability score of 1 (reliable without restriction).	Anonymous, 2010c. ECHA dissemination site, 2021.
OECD 9.1, EEC (9.2) and ISO	*P.subcapitata*	Lucidol (Dibenzoyl peroxide)	E_rC_{50} (72 hr, static, WAF): 0.83 mg/L	Supporting study.	Anonymous, 1999b.

Guidelines, (9.3) and ECETOC Monograph 26 (9.4)		Purity: Information not available WAF: negative control, undiluted WAF, 1:2, 1:4, 1:8 and 1:16 and 1:32 WAF dilutions	E_bC_{50} (72 hr, static, WAF): 0.44 mg/L	GLP compliant. Deviations: The $NaHCO_3$ concentration of the test medium was 150 mg/L instead of 50 mg/L, as recommended by the OECD/EEC Guidelines, in order to maintain a more constant pH during the test. It is stated the pH should not deviate more than 1.5 units during the test (EEC). The WAF method was used in the form of as a series of dilutions. Reliability score of 3 (not reliable).	ECHA dissemination site, 2021.
OECD 201	*P.subcapitata*	Dibenzoyl peroxide Purity: 79.4% Test concentration (mg/L) Nominal: 0.05, 0.1, 0.2, 0.4 and 0.8.	E_rC_{50} (72 hr, static): 0.44 mg/L. E_bC_{50} (72 hr, static): 0.07 mg/L	Supporting study. GLP status: not reported. Source of test species unknown. Insufficient information available to evaluate the test design, conditions, and validity. Reliability score of 4 (not	Anonymous, 2001b. ECHA dissemination site, 2021.

				assignable).	

11.5.1 Acute (short-term) toxicity to fish

The acute toxicity of dibenzoyl peroxide to fish was assessed in four acute toxicity studies using different fish species and in accordance with international standards or accepted guidelines, equivalent to the OECD 203 guideline. Three of the four studies were GLP compliant.

The acute toxicity of dibenzoyl peroxide to *Oncorhynchus mykiss* (rainbow trout) was investigated under semi-static conditions (daily renewal) for 96 hours (Anonymous, 2010a). Following a preliminary range-finding study, juvenile rainbow trout were exposed for 96 hr to an aqueous solution of dibenzoyl peroxide at different nominal concentrations of 0.427, 0.939, 2.07, 4.55 and 10 mg/L (geometric mean measured concentrations of 0.0081, 0.0097, 0.0224, 0.0316 and 0.0741 mg/L). All validity criteria, as set out in the OECD 203, were fulfilled. Hyperventilation was observed at the highest test concentration (10 mg/L nominal) in 1/7 fish after 72 hours and 2/7 fish after 96 hr. No mortalities were observed. The dossier submitter notes that the actual exposure concentrations of dibenzoyl peroxide were significantly lower than the nominal concentrations used in the test, especially at the higher test concentrations. This, in part, may have been influenced by the physicochemical properties of the substance such as the low water solubility (0.35 mg/L), high absorptive potential (log Koc 3.8) and the unstable nature of dibenzoyl peroxide in water. The study summary reports, based on the conditions of the study, the 96 hr (semi-static) LC_{50} and NOEC of rainbow trout exposed to dibenzoyl peroxide to be 0.0602 mg/L and 0.0316 mg/L (mean measured), respectively.

The acute toxicity of dibenzoyl peroxide to *Poecilia reticulata* (Guppy) fish was investigated under aerated semi-static conditions for 96 hours at nominal concentrations of 0.7, 1.3, 2.4 and 4.2 mg/L following a dose range finding study (Anonymous, 1989). In the highest treatment group, 4.2 mg/L (nominal), 100% mortality was observed after 4 hr. In addition, 10% (1/10) and 70% (7/10) mortality was reported in the 1.3 and 2.4 mg/L (nominal) treatment groups after 48 hr, respectively. The study summary reports, based on the conditions of the study, the estimated 96 hr LC_{50} and NOEC of dibenzoyl peroxide for guppy fish, based on nominal concentrations, to be 2 mg/L (95% C.I. 1.7 and 2.4 mg/L) and 0.7 mg/L, respectively. The study summary indicates that the test species were obtained from a local aquarium retailer and therefore the provenance is uncertain and not in line with the recommendations of the test guideline. The life-stage of the test species is unknown, the length of the test organisms exceeded the recommendations of the test guideline (3 cm vs recommended length range of 1-2 cm, rationale not provided), and analytical monitoring was not performed. The study deviated from the recommendations of the OECD 203 guideline. The validity criteria as set out in the OECD 203 guideline were not fulfilled. Based on the above considerations, the dossier submitter agrees with the registrant's conclusion and considers that the study is not reliable. Refer to section 4.3.1 of Annex I to this CLP report for further study details.

The acute toxicity of dibenzoyl peroxide to *Oryzias latipes* (Japanese medaka) fish was investigated under continuous flow-through conditions for 96 hours (Anonymous, 2002). Fish were exposed to nominal concentrations of 0.25, 0.5, 1.0, 2.0 and 4 mg/L dibenzoyl peroxide (mean measured concentrations of 0.23, 0.47, 0.69, 1.54 and 2.17 mg/L). Precipitation of the test substance was observed at the surface of the test medium at 0.47 mg/L (mean measured) and 2.17 mg/L (mean measured) test concentrations. No mortality was observed in the controls or the 0.23 mg/L (mean measured) test group at the end of the study period. 100 % mortality was observed at 24 hr in the 1.54 and 2.17 (mean measured) mg/L test groups, at 48 hr for the 0.69 (mean measured) mg/L test group, and at 72 hr for the 0.47 (mean measured) mg/L test group. Under the conditions of the study, the 96 hr LC_{50} and NOEC of dibenzoyl peroxide for Japanese medaka fish, based on mean measured concentrations, were estimated to be 0.24 mg/L (95% C.I. 0.20 and 0.27 mg/L) and 0.23 mg/L, respectively. The study summary indicates that the source of the test species was unknown. The length of the test species was outside of the recommended range (3.5 cm vs recommended length range of 1-2 cm, rationale not provided). According to the literature, the body length of Japanese medaka at sexual maturity ranges from between 2.5-3 cm (Shiema et al., 2004). The dossier submitter agrees the identified points as reported in the study summary are deviations from the recommendations of the OECD 203 guideline. There is no further information reported in the study summary to assess against the validity criteria in accordance with the OECD 203 guideline. Based on the above considerations, the dossier submitter considers that the study is not reliable. Refer to section 4.3.1 of Annex I for further study details.

The acute toxicity of dibenzoyl peroxide to *Oryzias latipes* (Japanese medaka) fish was investigated in a non-GLP compliant study, under static conditions for 96 hours (Anonymous, 1996). Information on the test species, test concentrations, conditions, and design are not reported in the study summary. The study summary reports a 96 hr LC_{50} of 3.9 mg/L for Japanese medaka fish exposed to dibenzoyl peroxide. As no further information is reported in the study summary, the dossier submitter does not consider the study reliable.

In summary, the dossier submitter considers the 96 hr LC_{50} for *Oncorhynchus mykiss* (Anonymous, 2010a) (96 hr LC_{50} = 0.0602 mg/L (mean measured)) to be the lowest reliable value for this trophic level.

Data used for classification: Fish 96 hr LC_{50} = 0.0602 mg/L (mean measured)

11.5.2 Acute (short-term) toxicity to aquatic invertebrates

The acute toxicity of dibenzoyl peroxide to aquatic invertebrates (*Daphnia magna*) was investigated in three acute toxicity studies and in accordance with international standards or accepted guidelines, equivalent to the OECD 202. All three studies were GLP compliant.

The acute toxicity (immobilisation) of dibenzoyl peroxide to *Daphnia magna* was investigated under static conditions for 48 hours (Anonymous, 2010b). Following a preliminary range finding study, neonate daphnids were exposed for 48 hr to an aqueous solution of dibenzoyl peroxide at nominal concentrations of

0.427, 0.939, 2.07, 4.55 and 10 mg/L (mean measured: <LOQ, < LOQ, 0.0416, 0.0765 and 0.157 mg/L). Analytical monitoring was performed. Measured concentrations of dibenzoyl peroxide were significantly lower than the nominal concentrations used in the test, especially at the higher test concentrations. The concentration of dibenzoyl peroxide in the fresh samples was determined to be between 0 - 2% of the nominal concentrations. Dibenzoyl peroxide was not detectable in the expired samples (48 hr). Benzoic acid concentrations were detected in the fresh samples, but were undetectable in the expired solutions. The validity criteria as set out in OECD 202 were fulfilled. No mortalities were observed. The study summary reports that, under the conditions of the study, the estimated 48 hr EC_{50} and NOEC of dibenzoyl peroxide to *Daphnia magna* to be 0.110 mg/L (mean measured) (95% confidence limits of 0.0765 and 0.157 mg/L) and 0.0765 mg/L (mean measured), respectively.

The acute toxicity of dibenzoyl peroxide to *Daphnia magna* was investigated under static conditions using WAF serial dilutions for 48 hours (Anonymous, 1999a). Neonate daphnids were exposed to a negative control, undiluted WAF and 1:2, 1:4, 1:8 and 1:16 WAF dilutions of dibenzoyl peroxide solution. The WAF EC_{50} and NOEC (48 hr) of dibenzoyl peroxide to *Daphnia magna* were estimated to be 2.91 mg/L (95% confidence limits of 2.71-3.11 mg/L) and 1.99 mg/L, respectively. Although the validity criteria of the study appear to be fulfilled, the dossier submitter does not consider the study to be reliable for the following reasons: the WAF method was used in the form of a series of dilutions. ECHA's *Information Requirements Chapter R.7b: Endpoint Specific Guidance (2017)*, indicates that the WAF test method is generally used for substances that contain many constituents or for any substance with very low water solubility. It also indicates that all efforts should first be made to produce a reliable and stable test concentration, and only if this is not feasible, due to the properties of the substance or due to disproportionate efforts, can the WAF be considered as a last resort to generate exposure in a test. The guidance also indicates that the method used to prepare the WAF should be fully described in the test report, with evidence provided of attainment of equilibrium and its compositional stability over time if possible. It also stated that WAFs are to be prepared individually and not by serial dilution of a single WAF stock. The dossier submitter notes that the WAF dilutions were prepared from serial dilutions and monitoring was performed at the beginning and end of the test only. No further information is reported in the study summary to indicate that the WAF method was the last resort. The reported effective test concentration was well above the water solubility of the substance. Finally, there is no further information reported in the robust study summary to determine if the test substance concentration was maintained throughout the study. Considering this, the dossier submitter does not consider the study to be reliable. Refer to section 4.3.2 of Annex I for further details on the study.

The acute toxicity of dibenzoyl peroxide to *Daphnia magna* was investigated under static conditions for 48 hours (Anonymous, 2001a). At 48 hr, 100% immobilisation was observed in the 0.13, 0.25 and 0.50 mg/L test groups while 10% immobilisation was observed in the 0.06 mg/L. The nominal 48 hr EC_{50} of dibenzoyl peroxide to *Daphnia magna* was estimated to be 0.07 mg/L. No further information is reported in the study

summary on the test conditions, design, and results. The dossier submitter does not consider the study to be reliable.

In summary, the dossier submitter considers the 48 hr EC_{50} for *Daphnia magna* (Anonymous, 2010b) (48 hr EC_{50} = 0.110 mg/L (mean measured)) to be the lowest reliable value for this trophic level.

Data used for classification: aquatic invertebrates 48 hr EC_{50} = 0.110 mg/L (mean measured)

11.5.3 Acute (short-term) toxicity to algae or other aquatic plants

The acute toxicity of dibenzoyl peroxide to algae was investigated in three acute toxicity studies conducted in accordance with international standards or accepted guidelines, equivalent to OECD 201. Two of the three studies were GLP compliant.

The acute toxicity (growth inhibition) of dibenzoyl peroxide to *Pseudokirchneriella subcapitata* was investigated under static conditions for 72 hours (Anonymous, 2010c). Based on the results of a preliminary range finding study, algae were exposed to nominal test concentrations of 0.427, 0.939, 2.07, 4.55 and 10 mg/L (0.034, 0.102, 0.166, 0.296, and 0.842 mg/L measured as benzoic acid). The validity criteria, as set out in the OECD 201, were fulfilled. Measured concentrations of dibenzoyl peroxide were significantly lower than the nominal concentrations used in the test, especially at the higher test concentrations. The concentration of dibenzoyl peroxide in the fresh samples were determined to be between 0 - 2% of the nominal concentrations. Dibenzoyl peroxide was not detectable in the expired samples (72 hr). Benzoic acid concentrations were detected in the fresh samples but were undetectable in the expired solutions except in the two highest test concentrations. The study summary reports that no microscopic abnormalities of the cells were detected. The study summary reports that, under the conditions of the study, the 72 hr E_bC_{50}, E_rC_{50}, E_yC_{50}, and NOEC of dibenzoyl peroxide to algae were 0.0422 mg/L, 0.0711 mg/L, 0.0724 mg/L and 0.02 mg/L respectively, based on initial measured concentrations in the fresh samples.

The acute toxicity of Lucidol (dibenzoyl peroxide) to *Pseudokirchneriella subcapitata* was investigated under static conditions using WAF serial dilutions for 72 hours (Anonymous, 1999b). Algae were exposed to a negative control, undiluted WAF, and 1:2, 1:4, 1:8, 1:16 and 1:32 WAF dilutions of Lucidol solution. Chemical analysis of the test concentration were performed using NPOC (non-purgeable organic carbon). Under the conditions of the study, the WAF E_bC_{50} and E_rC_{50} (72 hr) of dibenzoyl peroxide to algae (*Pseudokirchneriella subcapitata*), based on indicative concentrations, were estimated to be 0.44 mg/L (0.31-0.62 mg/L 95% confidence limits) and 0.83 mg/L (0.59-1.13 mg/L 95% confidence limits), respectively. The study summary reports that an indicative NOEC and LOEC of 0.12 mg/L and 0.23 mg/L were determined, respectively. Based on the information reported in the study summary the dossier submitter does not consider it possible to determine if the validity criteria of the study were fulfilled. In addition, the test concentrations were determined by NPOC analysis. The dossier submitter notes that NPOC analysis is not a specific method for the test compound and therefore the results can only be used as an indication of the

concentration of the test material present. The WAF method was used in the form of a series of dilutions. ECHA's *Information Requirements Chapter R.7b: Endpoint Specific Guidance (2017)*, indicates that the WAF test method is generally used for substances that contain many constituents or for any substance with very low water solubility. It also indicates that all efforts should first be made to produce a reliable and stable test concentration, and only if this is not feasible, due to the properties of the substance or due to disproportionate efforts, can the WAF be considered as a last resort to generate exposure in a test. No further information is reported in the study summary to indicate that the WAF method was the last resort. Based on the above considerations, the dossier submitter does not consider the study reliable. Refer to section 4.3.3 of Annex I for further details on the study.

In a final acute toxicity study on algae, *Pseudokirchneriella subcapitata*, were exposed to nominal concentrations of dibenzoyl peroxide (0.05, 0.1, 0.2, 0.4 and 0.8 mg/L) under static conditions for 72 hours (Anonymous, 2001b). Under the conditions of the study the nominal 72 hr E_bC_{50} and E_rC_{50} of dibenzoyl peroxide to algae, were estimated to be 0.07 mg/L and 0.44 mg/L, respectively. The dossier submitter considers, based on the information reported in the study summary on the test design, conditions, results and validity, that the study is not reliable. Please refer to section 4.3.3 of Annex I for further details on the study.

In summary, the dossier submitter considers the 72 hr E_rC_{50} for *Pseudokirchneriella subcapitata* (Anonymous, 2010c) (72 hr E_rC_{50} = 0.0711 mg/L (ini. measured)) to be the lowest reliable value for this trophic level.

Data used for classification: algae 72 hr E_rC_{50} = 0.0711 mg/L (ini. measured).

11.5.4 Acute (short-term) toxicity to other aquatic organisms

No relevant data available.

11.6 Long-term aquatic hazard

Table 12: Summary of relevant information on chronic aquatic toxicity

Method	Species	Test material	Results	Remarks	Reference
Fish					
No data available.					
Aquatic Invertebrates					
OECD 211	*Daphnia magna*	Dibenzoyl peroxide Purity: 74.2%	EC_{10} (reproduction): 0.001 mg/L (95%C.I. 0.00010-0.0018) (semi-static, TWA mean measured). NOEC (reproduction): 0.0011 mg/L (semi-	Key study. GLP compliant. No deviations reported.	Anonymous, 2015a. ECHA dissemination site, 2021.

		Test conc.: Nominal: 3.2, 5.6, 10, 18 and 32% v/v saturated solution. Time-weighted average (TWA) mean measured: 0.00062, 0.0011, 0.0016, 0.0028 and 0.0074 mg/L.	static, TWA mean measured). 50% (statistically significant) mortality (immobilization) at 0.0028 and 0.0074 mg/L (mean measured). Statistically significant reduction in no. live offspring/adult in test groups 0.0016, 0.0028 and 0.0074 mg/L. Observations: a number of parent daphnia reported as pale at all test conc. compared to the control.	Reliability score of 1 (reliable without restriction).	
Aquatic Algae					
Method	**Species**	**Test material**	**Results**	**Remarks**	**Reference**
OECD 201, EU Method C.3	*P.subcapitata*	Dibenzoyl peroxide Purity: 74.6% Test concentrations (mg/L): Nominal: 0.427, 0.939, 2.07, 4.55 and 10. Measured (initial): 0.034, 0.102, 0.166, 0.296, and 0.842 (benzoic acid expressed as dibenzoyl peroxide).	NOEC (72 hr, static): 0.02 mg/L (ini. measured).	Key study. GLP compliant. No deviations reported. Reliability score of 1 (reliable without restriction).	Anonymous, 2010c. ECHA dissemination site, 2021.
OECD 9.1, EEC (9.2) and ISO Guidelines, (9.3) and ECETO	*P.subcapitata*	Lucidol (Dibenzoyl peroxide) Purity: information not available WAF: negative control, undiluted	NOEC (72 hr, static, WAF): 0.12 mg/L. LOEC (72 hr, static, WAF): 0.23 mg/L.	Supporting study. GLP compliant. Deviations: The $NaHCO_3$ concentration of the test	Anonymous, 1999b. ECHA dissemination site, 2021.

C Monograph 26 (9.4)		WAF, 1:2, 1:4, 1:8 and 1:16 and 1:32 WAF dilutions		medium was 150 mg/L instead of 50 mg/L, as recommended by the OECD/EEC Guidelines, in order to maintain a more constant pH during the test. It is stated the pH should not deviate more than 1.5 units during the test (EEC). The WAF method was used in the form of as a series of dilutions. Reliability score of 3 (not reliable).	

11.6.1 Chronic toxicity to fish

No relevant data available.

11.6.2 Chronic toxicity to aquatic invertebrates

One long-term freshwater toxicity test on aquatic invertebrates is available (Anonymous, 2015a), investigating the effects of dibenzoyl peroxide on the reproductive output of *Daphnia magna* according to OECD 211. Daphnids (< 24 hr old at the start of the test, 10 individuals per treatments, held individually) were exposed to dibenzoyl peroxide under semi-static conditions for 21 days. The saturated solution method was used to prepare the test solution. A nominal amount of test material (20 mg) was dispersed in 2 litres of test water with the aid of sonication for 30 minutes. Undissolved test substance was removed by filtration through a 0.2 µm Gelman Acrocap filter to give a 100% v/v saturated solution. A series of dilutions were made from this saturated solution to give the required test concentrations of 3.2, 5.6, 10, 18 and 32% v/v (nominal) saturated solution, corresponding to time-weighted mean measured test concentrations of 0.00062, 0.0011, 0.0016, 0.0028 and 0.0074 mg/L. The test solution was renewed daily. The control group was maintained under identical conditions with the exception of being exposed to the test substance. The concentration and stability of the test substance in the test preparations were verified by chemical analysis on

days 0, 1, 6, 7, 13, 14, 20 and 21. Water quality measurements and temperature were monitored throughout the test. Daily observations were made on the number of dead/surviving adult daphnids, dead/surviving offspring, and the number of discarded unhatched eggs. The general condition and size of the parental daphnia was assessed and compared with the controls. The number of daphnia with eggs or young in the brood pouch was determined daily. At the end of the test, the length of each surviving parent animal was determined. The percentage parental survival and total number of live young exposed to dibenzoyl peroxide for 21 days are reported in Table 13.

Table 13: Parental survival and total number of live young following exposure of *Daphnia magna* to dibenzoyl peroxide for 21 days (Anonymous, 2015a, ECHA Dissemination site, 2021)

Nominal (%v/v saturated solution)	Mean Measured (TWA mg/L)	P1 Generation % Survival (mortality)	Total No. Live Young	Total No. Live Young ex. Replicates with Parental Accidental or Inadvertent Mortalities*	No. Live Young/Parent at start of test ex. Replicates with Parental Accidental or Inadvertent Mortalities*
Control	Control	100 (0)	1083	1046	116
3.2	0.00062	80 (20)	924	892	112
5.6	0.0011	89 (11)	1056	900	113
10	0.0016	90 (10)	862	862	96**
18	0.0028	50 (50)	593	593	59**
32	0.0074	50 (50)	363	363	36**

* Excluding Replicates with Parental Accidental and/or Inadvertent Mortalities

** Statistically significant difference (reduction) in the number of live offspring per adult compared to the control.

Significant mortality (immobilization) was observed at test concentrations of 0.0028 and 0.0074 mg/L (mean measured) resulting in 50% mortality in both test groups by Day 21 indicating a prolonged toxic effect following exposure of *Daphnia magna* to dibenzoyl peroxide. Lower levels of immobilisation, between 10 and 20%, were observed at the test concentrations of 0.00062, 0.0011 and 0.0016 mg/L (mean measured). Throughout the test, some of the parent daphnia, in all test concentrations, were observed as pale when compared to the control daphnia. The robust study summary reports that there were no statistically significant differences (P 0.05) between the control and each test group in terms of length of the daphnids after 21 days exposure to the test substance. The results of the time to first brood, the time to production of first brood, and the average body lengths of the 1st generation surviving adults were not reported. After 21 days there were no statistically significant differences in the number of live offspring produced per adult between the control and the 0.00062 and 0.0011 mg/L test groups. There was a statistically significant reduction in the number of live offspring per adult in the 0.0016, 0.0028 and 0.0074 mg/L test groups (mean

measured) when compared to the control after 21 days. The total number of live offspring per adult recorded for the 0.0016, 0.0028 and 0.0074 mg/L test groups were 96, 59 and 36 respectively while the control group recorded 116 live offspring per adult.

The validity criteria, as set out in the OECD 211, were fulfilled. The mortality in the control group of adult *Daphnia magna* was 0%; the mean number of offspring produced per control adult was 116; and the coefficient of variation around the mean number of offspring produced per control adult was 13.5%.

Under the conditions of the study, an EC_{10} (reproduction) of 0.001 mg/L (95% C.I. 0.00010-0.0018), based on the time-weighted mean measured test concentrations, was determined for *Daphnia magna* exposed to dibenzoyl peroxide for 21 days. A NOEC (reproduction) of 0.0011 mg/L (TWA mean measured) was also derived based on the statistically significant differences (reduction) in the number of live offspring per adult compared to the control after 21 days.

Data used for classification: invertebrates EC_{10} = 0.001 mg/L (TWA mean measured)

11.6.3 Chronic toxicity to algae or other aquatic plants

Please refer to section 11.5.3.

11.6.4 Chronic toxicity to other aquatic organisms

No relevant data available.

11.7 Comparison with the CLP criteria

11.7.1 Acute aquatic hazard

Table 14: Comparison with criteria for acute aquatic hazards

	Criteria for acute environmental hazards	Dibenzoyl peroxide	Conclusion
Acute Aquatic Toxicity	Category 1: $LC_{50}/EC_{50}/E_rC_{50} \leq 1$ mg/L	Fish: 96 hr LC_{50} = 0.0602 mg/L (mean measured) (*Oncorhynchus mykiss)* Invertebrates: 48 hr LC_{50}= 0.110 mg/L (mean measured) (*Daphnia magna*) Algae: 72 hr E_rC_{50}= 0.0711 mg/L (ini. measured) (*P.subcapitata*)	**Aquatic Acute 1,** **M factor=10**

Acute toxicity studies are available for all three trophic levels. The results presented in Table 14 above and discussed in more detail in sections 11.5.1 to 11.5.3, demonstrate that dibenzoyl peroxide is acutely toxic to fish, invertebrates and algae with all endpoints below 1 mg/L (< 1mg/L) for all three species.

The CLP Regulation sets a criteria value of < 1 mg/L for hazard category 1 acute toxicity. In accordance with the CLP Regulation, the most protective and valid short-term toxicity endpoint (LC_{50} or EC_{50}) should be compared to the acute toxicity criteria and used for classification purposes. The dossier submitter considers the 96 hr LC_{50} of 0.0602 mg/L (mean measured) for fish, *Oncorhynchus mykiss*, to be the lowest reliable acute effect concentration. Dibenzoyl peroxide fulfils the criteria for classification as Category 1 Aquatic Acute; H400 '*Very toxic to aquatic life'* according to the CLP Regulation. In accordance with Annex I: Table 4.1.3 of the CLP Regulation, for mixture toxicity, a corresponding M factor of 10 is applicable for an acute toxicity endpoint between 0.01 and 0.1 mg/L.

11.7.2 Long-term aquatic hazard (including bioaccumulation potential and degradation)

Table 15: Comparison with criteria for long-term aquatic hazards

	Criteria for acute environmental hazards	**Dibenzoyl peroxide**	**Conclusion**
Rapid degradation	Half-life hydrolysis < 16 days Readily biodegradable in a 28 day test for ready biodegradability (> 70 % DOC removal or > 60 % theoretical oxygen demand, theoretical carbon dioxide)	Hydrolytically unstable Half-life < 24 hr 68 % ThOD after 28 days = readily biodegradable	**Rapidly degradable**
Bioaccumulation	log Kow ≥ 4 BCF ≥ 500	log Kow 3.43 (estimated) log Kow = 3.2 (measured) BCF = 89.11 L/kg (estimated)	**Low potential for bioaccumulation**
Aquatic toxicity	*Chronic toxicity:* Rapidly degradable substances: Cat. 1: EC_x or NOEC ≤ 0.01 mg/L Cat. 2: EC_x or NOEC ≤ 0.1 mg/L Cat. 3: EC_x or NOEC ≤ 1 mg/L	Invertebrates: 21 day EC_{10} = 0.001 mg/L (*Daphnia magna*) Algae: 72 hr NOEC = 0.02 mg/L (static) (*P. subcapitata*)	**Aquatic Chronic 1,** **M factor=10** *(based on invertebrate EC_{10})*

Dibenzoyl peroxide is considered rapidly degradable based on the results from the available ready biodegradability studies (68% degradation after 28 days) and hydrolysis study (half-life < 24 hr; rapidly hydrolyses). There is no available experimental information on the bioaccumulation of dibenzoyl peroxide. The measured (OECD 117 octanol-water partition coefficient study) and estimated (predictive modelling) log Kow values are below the cut-off criteria of 4. Dibenzoyl peroxide has an estimated BCF value of < 100 which is less than the CLP BCF criteria of ≥ 500. Therefore, dibenzoyl peroxide can be considered to have a low bioaccumulation potential for classification purposes. The dossier submitter notes that benzoic acid (EC No. 200-618-2) is considered the main degradation product of dibenzoyl peroxide. The available data for benzoic acid, as reported in the REACH registration dossier, indicates that benzoic acid can be considered as readily biodegradable and has a low bioaccumulation potential (ECHA dissemination site, 2021b).

One valid long-term toxicity study is available for aquatic invertebrates, a 21 day semi-static freshwater reproduction study was performed with *Daphnia magna*. A 72 hr freshwater static algae study, reporting an NOEC of 0.02 mg/L (ini. measured), is also available (Anonymous, 2010c). Based on the available long-term data and the physical-chemical properties of dibenzoyl peroxide (rapidly degradable; BCF < 500; log Kow < 4) the use of the surrogate approach for chronic classification is not considered appropriate.

The CLP Regulation sets a criteria value of ≤ 0.01 mg/L (rapidly degradable substances) for hazard category 1 chronic toxicity. In accordance with the CLP Regulation, the most protective and valid long-term toxicity endpoint (EC_x or NOEC) should be compared to the chronic toxicity criteria and used for classification purposes. The 21 day EC_{10} of 0.001 mg/L dibenzoyl peroxide (mean measured) for invertebrates, *Daphnia magna*, is the lowest effect concentration. Dibenzoyl peroxide fulfils the criteria for classification as Category 1 Aquatic Chronic; H410 '*Very toxic to aquatic life with long lasting effects'* according to CLP Regulation for a rapidly degradable substance. For mixture toxicity, a corresponding M factor of 10 is applicable for a chronic toxicity endpoint between < 0.0001 and ≤ 0.001 mg/L (rapidly degradable substances).

11.8 CONCLUSION ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS

Acute Aquatic Hazards:

Dibenzoyl peroxide is acutely toxic to fish, invertebrates and algae. In accordance with the CLP Regulation, the most protective and valid short-term toxicity endpoint for classification purposes (i.e. LC_{50} or EC_{50}) is the 96 hr LC_{50} of 0.0602 mg/L (mean measured) for fish, *Oncorhynchus mykiss*. Dibenzoyl peroxide fulfils the criteria for the classification as Category 1 Aquatic Acute; H400 '*Very toxic to aquatic life'* according to CLP Regulation. The corresponding M factor for an acute endpoint between 0.01 and 0.1 mg/L to be considered for mixture toxicity is 10 (M=10).

Chronic Aquatic Hazards:

Dibenzoyl peroxide is rapidly degradable and has a low potential to bioaccumulate. Dibenzoyl peroxide is chronically toxic to invertebrates, with the most protective valid long-term toxicity EC_{10} and NOEC of 0.001 mg/L (mean measured) and 0.0011 mg/L (mean measured), respectively. Dibenzoyl peroxide fulfils the criteria for the classification as Category 1 Aquatic Chronic; H410 '*Very toxic to aquatic life with long lasting effects'* according to CLP Regulation for a rapidly degradable substance. The corresponding M factor for a chronic endpoint between < 0.0001 and ≤ 0.001 mg/L for a rapidly degradable substance to be considered for mixture toxicity is 10 (M=10).

12 EVALUATION OF ADDITIONAL HAZARDS

Not evaluated as part of this dossier.

13 ADDITIONAL LABELLING

Not applicable.

14 REFERENCES

- ECHA (2021a): Dibenzoyl peroxide registration dossier (accessed August 2021) https://echa.europa.eu/registration-dossier/-/registered-dossier/15164
- ECHA (2021b): Benzoic acid registration dossier (accessed August 2021) https://echa.europa.eu/registration-dossier/-/registered-dossier/13124
- Anonymous (1989): Acute Toxicity of Dibenzoyl peroxide to fish. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (1999a): Acute Toxicity of Lucidol to Daphnia magna. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (1990): Biodegradability of Dibenzoyl peroxide. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (2015b): Biodegradability of Dibenzoyl peroxide (CAS No. 94-36-0) in the Closed Bottle Test (OECD 301D). (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (1992): Biodegradation and Bioaccumulation Data of Existing Chemicals Based on the CSCL. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (2010d): Dibenzoyl peroxide Abiotic Degradation: Hydrolysis as a Function of pH (Preliminary Test) (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (2010b): Dibenzoyl peroxide: Acute Toxicity to *Daphnia magna*. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (2010a): Dibenzoyl peroxide: Acute Toxicity to Fish. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (2010c): Dibenzoyl peroxide Algal Growth Inhibition Assay. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (2015a): Dibenzoyl peroxide (CAS No. 94-36-0): *Daphnia magna* Reproduction test. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (2009a): Dibenzoyl peroxide – Adsorption Coefficient (Koc) on Soil and Sewage Sludge. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (2009b): Dibenzoyl peroxide – Partition Coefficient (n-octanol/water) HPLC Method. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (2009c): Dibenzoyl peroxide – Ready Biodegradability – Closed Bottle Test. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (1999b): Effects of the Water Accommodated Fraction of Lucidol on the Growth of the Freshwater Green Alga *Pseudokirchneriella subcapitata*. (Unpublished report). ECHA Dissemination site 2021.
- Anonymous (1996): Establishment of Advanced Testing Methods for Hazardous Chemicals. ECHA Dissemination site 2021.

- Anonymous (2001a): The Acute Toxicity of Benzoyl peroxide to Aquatic Invertebrates (*Daphnia*). ECHA Dissemination site 2021.
- Anonymous (2002): The Acute Toxicity of Benzoyl peroxide to Fish. ECHA Dissemination site 2021.
- Anonymous (2001c): The Test of Benzoyl peroxide Hydrolysis as a Function of pH. ECHA Dissemination site 2021.
- Anonymous (2001b): The Toxicity of Benzoyl peroxide to Aquatic plants (algae). ECHA Dissemination site 2021.
- ECHA (2017): Guidance on the application of the CLP criteria.
- Klimisch H.J., Andreae M., and Tillmann U. (1997): A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25 (1), 1-5. DOI: 10.1006/rtph.1996.1076.
- Shima, A. and Mitani, H. (2004). Medaka as a research organism: past, present and future. Elsevier. Mechanisms of Development 121 (2004) 599-604.

15 ANNEX 1

Detailed study summaries for degradation, acute and chronic toxicity.