

Product Regulatory Information Document

PERKADOX L-DFG

Version 1.0 Revision Date 02.06.2021 Print Date 02.06.2021 REG_WORLD / EN

Trade name : PERKADOX L-DFG
 Common Name : Organic peroxide
 Pure substance/mixture : Substance
 Use of the Substance/Mixture : Specific use(s): Pharmaceutical ingredient

Company : Nouryon, Technology Solutions, Polymer Catalysts

General statement

The Company hereby certifies that the product can be lawfully used for the use(s) identified in this declaration within the limits set-up in the disclaimer that can be found at the end of the document. It is therefore advised to read the disclaimer carefully.

The present declaration must be read in conjunction with the Safety Data Sheet of the product which is the primary source of documentation, providing basic information about the properties, hazards, how to use the product safely and what to do in case of emergency.

Special substances of concern

Substance / Component	Concentration	Remarks
Sb: antimony		Not to the best of our knowledge
As: Arsenic		Not to the best of our knowledge
Ba: Barium		Not to the best of our knowledge
Be: Beryllium		Not to the best of our knowledge
Cd: cadmium		Not to the best of our knowledge
Cr: chromium		Not to the best of our knowledge
Co: Cobalt		Not to the best of our knowledge
Cu: Copper		Not to the best of our knowledge
Pb: Lead		Not to the best of our knowledge
Mn: Manganese		Not to the best of our knowledge
Hg: Mercury		Not to the best of our knowledge
Mo: Molybdenum		Not to the best of our knowledge
Ni: Nickel		Not to the best of our knowledge
Se: selenium		Not to the best of our knowledge
Ag: Silver		Not to the best of our knowledge
Te: Tellurium		Not to the best of our knowledge
Tl: Thallium		Not to the best of our knowledge
Sn: Tin		Not to the best of our knowledge

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V: Vanadium		Not to the best of our knowledge
Zn: Zinc		Not to the best of our knowledge
Adsorbed organic bound halogens (AOX)		Not to the best of our knowledge
Alkylphenol and alkylphenol ethoxylates		Not to the best of our knowledge
Amines, aromatic		Not to the best of our knowledge
Bisphenol		Not to the best of our knowledge
Butylated hydroxytoluene (BHT)		Not to the best of our knowledge
Dioxane		Not to the best of our knowledge
Dioxins		Not to the best of our knowledge
Dye and pigments		Not to the best of our knowledge
EDTA and salts thereof		Not to the best of our knowledge
Formaldehyde releasing substances		Not to the best of our knowledge
Free Ethylene oxide		Not to the best of our knowledge
Free Propylene oxide		Not to the best of our knowledge
Genetically modified organisms (GMO)		Not to the best of our knowledge
Isothizoline(s)		Not to the best of our knowledge
Neutralising agent		Not to the best of our knowledge
Nonylphenol		Not to the best of our knowledge
Nonylphenol Ethoxylate		Not to the best of our knowledge
Pesticides.		Not to the best of our knowledge
Phenol		Not to the best of our knowledge
Phthalates		Not to the best of our knowledge
Polybrominated biphenyl (PBB)		Not to the best of our knowledge
Polybrominated biphenyl ether (PBDE)		Not to the best of our knowledge
Polychlorinated biphenyl or Polychlorinated triphenyls (PCB or PCT)		Not to the best of our knowledge
Perfluorinated chemicals (PFCS)		Not to the best of our knowledge
Polycyclic aromatic hydrocarbons (PAHs)		Not to the best of our knowledge
Residual solvents		Not to the best of our knowledge
Volatile organic compounds (VOC)		Not to the best of our knowledge
Organic tin		Not to the best of our knowledge
Other halogenated compounds		Not to the best of our knowledge
Organic peroxides	75 %	
Active Oxygen Content	4,95 %	
Biocide		Not to the best of our knowledge
Brominated flame retardant		Not to the best of our knowledge
Materials derived from animal origin		Not to the best of our knowledge
Materials derived from plant origin		Not to the best of our knowledge
Aluminum		Not to the best of our knowledge
Toluene		Not to the best of our knowledge
Xylene		Not to the best of our knowledge

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Benzene		Not to the best of our knowledge
Sulphites		Not to the best of our knowledge
Endocrine disruptor		Not to the best of our knowledge
Allergens (celery, crustaceans, eggs, fish, gluten, milk, peanuts, sesame seeds, soy beans, tree nuts, wheat)		Not to the best of our knowledge

Carcinogenicity (advisory bodies)

IARC	: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
NTP	: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Regulatory information

EU	OSPAR Chemicals of Concern	Compliant
EU	Directive 1999/13/EC on the limitation of emissions of volatile organic compounds	Neither banned nor restricted
EU	EU Directive 94/62/EC and its amending Directive 2004/12/EC on packaging and packaging waste	Compliant.
EU	EU Directive 2011/65/EU RoHS2 Restriction of Hazardous Substances in Electrical and Electronic Equipment	Compliant.
EU	EU SVHC - REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	Not applicable
EU	EU Directive 2009/48/EC on the safety of toys	Compliant.
EU	EU REACH - Annex XIV - REACH - List of substances subject to authorisation (Annex XIV)	Not applicable
EU	EC 1005/2009 - Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	Not applicable
EU	EU POP - Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	Not applicable
EU	EU Regulation (EC) No 1223/2009 on cosmetic products	Not applicable
EU	EU - Council Regulation (EC) No 1334/2000 on control of exports of dual-use items and technology	Not applicable
EU	EU Regulation (EC) No 273/2004 on drug precursors	Not applicable
EU	Directive 2012/19/EC (WEEE)	Not applicable
EU	EU - Cosmetic Directive 76/768/EC	Not applicable
EU	EU Directive 2000/53/EC and its amending Directive 2008/33/EC on End-of-Life Vehicles (ELV)	Compliant
EU	REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	Not applicable
EU	EU PIC - Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	Not applicable
US	US MA RTK - Massachusetts Right to Know List of	Listed

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	Chemicals and Hazard Classifications	
REG_WORLD	Switzerland. VOC Ordinance, Annex II (Products)	Not listed on the Swiss VOC (Volatile Organic Compound) Annex II
US	US. CONEG: Coalition of Northeastern Governors	Compliant.
US	US NJ RTK - New Jersey Right to Know Hazardous Substance List (RTK-HSL)	Listed
US	US PA RTK - Pennsylvania: Hazardous substance list	Listed
REG_WORLD	Global Automotive Declarable Substance List (GADSL)	Compliant.
US	DEA - US. Drug Enforcement Administration (DEA) Listed Precursor and Essential Chemicals (21 CFR 1310)	Not applicable
US	Minnesota Hazardous Substance	Listed
BR	BR DPF - Brazil. List of chemicals controlled by the Federal Police	Not applicable
REG_WORLD	CWC - International Chemical Weapons Convention (CWC) Schedules of Toxic Chemicals and Precursors	Not applicable
PH	Priority Chemical List (PCL)	Not applicable
PH	Chemical Control Order (CCO)	Not applicable
CN	Chinese RoHS Regulations	Not applicable
SG	Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations	Banned and/or restricted
JP	Japanese RoHS Regulations	Not applicable
ID	ID HAZHEA - Indonesia. Regulation of the Ministry of Health No. 472 of 1996 on the safeguarding of substances hazardous to health.	Not applicable
REG_WORLD	Safety of Toys, Norm EN 71-3, 2013	Not applicable
ID	Prohibited substances	Not applicable
REG_WORLD	Classified as dual use (ECN/ECCN 1C350)	Not applicable
ID	Restricted substances	Not applicable
ID	Hazardous substances approved for use	Not applicable
ID	Type of Hazardous Materials Restricted to Import, Distribution and Supervision	Not applicable
TH	TH HAZSUB - Hazardous Substance Act	Banned and/or restricted
TH	Emergency Decree on Controlling the Use of Volatile Substances	Not applicable
AU	Prohibition/Licensing Requirements	There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.
CL	CL DRUG - Decree 1358 - Establishment of rules governing the control measures of precursors and essential chemicals.	Not applicable
AR	AR DRUG - Control of precursors and essential chemicals for the preparation of drugs.	Not applicable

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EC	EC DRUG - Organic Law on Integral Prevention of Social and Economic Phenomenon of Drugs and of Regulation and Use Control of Listed Substances subject to Monitoring	Not applicable
VE	VE DRUG - Drug Law - Controlled Chemicals	Not applicable
PE	PE DRUG - Control Act of precursor chemicals and controlled products.	Not applicable
PA	PA DRUG - List of Precursors and Controlled Chemicals.	Not applicable
MX	MX DRUG - Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.	Not applicable
UY	UY DRUG - Decree 391-2002 Regulation for Precursors and Chemicals.	Not applicable
CR	CR DRUG - Law on Narcotics, Psychotropic Substances, Drugs of Unauthorized Use, Money-Laundering and Related Activities.	Not applicable
CO	CO DRUG - Regulations controlling the importation, manufacture, sale, distribution, transport and use of substances that may be used for the processing of addictive drugs.	Not applicable
SV	SV DRUGP - List of Medicines and Controlled Substances - Precursors and Chemical Substances Frequently Used for Illicit Production of Narcotics and Psychotropic Substances Subject to Control.	Not applicable
TR	Regulation on Persistent Organic Pollutants (Number 30595)	Not applicable
CN	Hazardous Chemicals for Priority Management under SAWS	Listed
CN	China Severely Restricted Toxic Chemicals for Import and Export	Not applicable
CN	CN HAZCHEM - Catalogue of Hazardous Chemicals	Listed
SG	SG PetrFlamMat - Fire Safety (Petroleum and Flammable Materials) Regulations	Not applicable
CH	CH PIC - PIC Ordinance, ChemPICO (814.82)	Not applicable
TR	KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17)	Not applicable
RS	Rule book on Bans and Restrictions of Production, Placing on the Market and Use of Chemicals (State Gazette, Nr. 90/2013, 25/2015, 2/2016, 44/2017, 36/2018, 9/2020)(Annex 1)	Not applicable

Regulatory Registrations and Certifications

Halal : No certificate in place.
Kosher : No certificate in place.

Information about other regulations

Other regulatory information Australia

Standard for the Uniform : Schedule 5
Scheduling of Medicines and
Poisons

Other regulatory information Canada

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Canadian lists

Canadian environmental protection act - National Pollutant Release Inventory

Canada. CEPA 1999 Significant New Activity (SNAc) List : Dibenzoyl peroxide 94-36-0
: No substances are subject to a Significant New Activity Notification.

Other regulatory information China

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : Listed

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)

Category	Threshold quantity
Organic peroxides	50 t

Hazardous Chemicals for Priority Management under SAWS : Listed

Other regulatory information European Union

NL: General Assessment Methodology (GAM)

Aquatic harmfulness : B1 Highly toxic for aquatic organisms.

Abatement effort : B Readily biodegradable aquatic harmful substances.

Water contaminating class (Germany) : WGK 1 slightly hazardous to water
Classification according to AwSV, Annex 1 (5.2)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	P6b	SELF-REACTIVE SUBSTANCES AND MIXTURES and ORGANIC PEROXIDES
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E1 ENVIRONMENTAL HAZARDS

Regulation on prevention of major industrial accidents. Reg number 30702	P6b	SELF-REACTIVE SUBSTANCES AND MIXTURES and ORGANIC PEROXIDES
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E1 ENVIRONMENTAL HAZARDS

TA Luft List (Germany) :

- Total dust: Not applicable
- Inorganic substances in powdered form: Not applicable
- Inorganic substances in vapour or gaseous form: Not applicable
- Organic Substances: portion Class 1: 77 %

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- Carcinogenic substances: Not applicable
- Mutagenic: Not applicable
- Toxic to reproduction: Not applicable

Volatile organic compounds : US. Clean Air Act Section 111 SOCM I Intermediate or Final Volatile Organic Compounds (VOC) - 40 CFR part 60.489
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

40 CFR 51.100(s) - Definition - Volatile Organic Compounds (VOC) Exemptions
This product does not contain any VOC exemptions listed under the U.S. Clean Air Act Section 450.

Other regulatory information Japan Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Other regulatory information United States of America (USA)

TSCA list

TSCA 5(a)(2) : No substances are subject to a Significant New Use Rule.
TSCA 12(b) : No substances are subject to TSCA 12(b) export notification requirements.

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA : This material does not contain any components with a CERCLA RQ.

SARA 304 : This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 : Organic peroxides
Respiratory or skin sensitisation
Serious eye damage or eye irritation

SARA 302 : This material does not contain any components with a section 302 EHS TPQ.

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:
Dibenzoyl peroxide 94-36-0 73 - 77 %

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals subject to disclosure and listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

List of Abbreviations

ACGIH	:	American Conference of Governmental Industrial Hygienists
CFR	:	Code of Federal Regulations
CMR	:	Carcinogenic Mutagenic and Reprotoxic
DID	:	Detergent Ingredient Database
EDTA	:	Ethylenediaminetetraacetic acid
EPA	:	Environmental Protection Agency
EU	:	European Union
IARC	:	International Agency for Research on Cancer
NTP	:	National Toxicology Program
OSHA	:	Occupational Safety and Health Administration
PFAS	:	Perfluoroalkyl sulfonate
PFCA	:	Perfluorocarboxylic acid
PFOA	:	Perfluorooctanoic acid
PFOS	:	Perfluorooctane sulfonate
REACH	:	Registration, Evaluation, Authorization and restriction of Chemicals
RoHS	:	Restriction of Hazardous Substances
SVHC	:	Substances of Very High Concern

Not Applicable : The product, and the substances within at the present concentrations, either does not fall under the limitations/requirements within the applicable statute for the regulation or the regulation is not applicable for the product and its application.

AR Argentina	AT Austria	BE Belgium	BR Brazil
CA Canada	CH Switzerland	CL Chile	CO Colombia
CR Costa Rica	DE Germany	DK Denmark	EC Ecuador
ES Spain	EU European Union	FI Finland	FR France
GB United Kingdom	ID Indonesia	IN India	IT Italy
JP Japan	MX Mexico	NL The Netherlands	PA Panama
PE Peru	PH Philippines	REG WORLD World	SE Sweden
SG Singapore	SV El Salvador	TH Thailand	TR Turkey
US USA	UY Uruguay	VE Venezuela	VN Vietnam

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