

# Product Regulatory Information Document TRIGONOX K-84 PG

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Trade name : TRIGONOX K-84 PG

Pure substance/mixture : Substance

Use of the : Specific use(s): Pharmaceutical

Substance/Mixture

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
TI: Thallium		Not to the best of our knowledge
Sn: Tin		Not to the best of our knowledge
V: Vanadium		Not to the best of our knowledge

Zn: Zinc		Not to the best of our knowledge
Adsorbed organic bound		Not to the best of our knowledge
halogens (AOX)		Not to the best of our knowledge
Alkylphenol and alkylphenol		Not to the best of our knowledge
ethoxylates		That 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
		Not to the best of our knowledge
Dye and pigments		
EDTA and salts thereof		Not to the best of our knowledge
Formaldehyde releasing		Not to the best of our knowledge
substances		Not to the heat 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		Not to the best of our knowledge
(GMO) Isothizoline(s)		Not to the heat of our knowledge
` '		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)	7 - 13 %	The the the poot of our fallemenge
Organic tin		Not to the best of our knowledge
Other halogenated compounds		Not to the best of our knowledge
Organic peroxides	82 - 86 %	That to the boot of our knowledge
Active Oxygen Content	8,62 - 9,04 %	
Biocide	0,02 - 3,04 70	Not to the best of our knowledge
		9
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		Not to the best of our knowledge
origin		
Aluminum		Not to the best of our knowledge
Toluene		Not to the best of our knowledge
Xylene		Not to the best of our knowledge
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 : Group 2B: Possibly carcinogenic to humans

Cumene 98-82-8

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 : Reasonably anticipated to be a human carcinogen

Cumene 98-82-8

# **Regulatory information**

EU	OSPAR List of Substances of Possible Concern	Compliant
EU	REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	Number: 3 Further information: See Annex XVII to Regulation (EC) no 1907/2006 for Conditions of restriction
EU	Directive 1999/13/EC on the limitation of emissions of volatile organic compounds	Banned and/or 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	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 Chemicals and Hazard Classifications	Listed

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REG_WO	Switzerland. VOC Ordinance, Annex II (Products)	listed on the Swiss VOC
RLD	US. CONEG: Coalition of Northeastern Governors	Annex II
US	US PA RTK - Pennsylvania: Hazardous substance	Compliant. Listed
	list	
REG_WO RLD	Global Automotive Declarable Substance List (GADSL)	Compliant.
US	Minnesota Hazardous Substance	Listed
US	DEA - US. Drug Enforcement Administration (DEA) Listed Precursor and Essential Chemicals (21 CFR 1310)	Not applicable
REG_WO RLD	CWC - International Chemical Weapons Convention (CWC) Schedules of Toxic Chemicals and Precursors	Not applicable
BR	BR DPF - Brazil. List of chemicals controlled by the Federal Police	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
REG_WO RLD	Safety of Toys, Norm EN 71-3, 2013	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
ID	Prohibited substances	Not applicable
REG_WO RLD	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	Listed
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
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	Not applicable
	Chemicals.	Tot application
MX	MX DRUG - Federal Law for the control of chemical	Not applicable
	precursors, essential chemical products and machinery for producing capsules, tablets and pills.	
UY	UY DRUG - Decree 391-2002 Regulation for	Not applicable
	Precursors and Chemicals.	
CR	CR DRUG - Law on Narcotics, Psychotropic	Not applicable
	Substances, Drugs of Unauthorized Use, Money- Laundering and Related Activities.	
СО	CO DRUG - Regulations controlling the importation,	Not applicable
	manufacture, sale, distribution, transport and use of	The state of the s
	substances that may be used for the processing of	
SV	addictive drugs.  SV DRUGP - List of Medicines and Controlled	Not applicable
S v	Substances - Precursors and Chemical Substances	Two applicable
	Frequently Used for Illicit Production of Narcotics	
TD	and Psychotropic Substances Subject to Control.	N. C. II.
TR	Regulation on Persistent Organic Pollutants (Number 30595)	Not applicable
CN	Hazardous Chemicals for Priority Management under SAWS	Not applicable
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	Number: 3
	manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Further information: See Annex 17 to KKDIK
	(Annex 17)	Regulation No.30105 (Bis)
		(23.06.2017) for Conditions of
DC	Dula hash as Dana and Dastriations of Dasduction	restriction
RS	Rule book on Bans and Restrictions of Production, Placing on the Market and Use of Chemicals (State	Number: 3 Further information: See the
	Gazette, Nr. 90/2013, 25/2015, 2/2016, 44/2017,	Rule book on Bans and
	36/2018, 9/2020)(Annex 1)	Restrictions of Production,
		Placing on the Market and
		Use of Chemicals (State Gazette, Nr. 90/2013,
		25/2015, 2/2016,44/2017,
		36/2018)(Annex 1) for
		Conditions of restriction

# **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 : No poison schedule number allocated

Scheduling of Medicines and

Poisons

Other regulatory information Canada

**Canadian lists** 

Canada. CEPA 1999 : No substances are subject to a Significant New Activity

Significant New Activity Notification.

(SNAc) List

Canadian Environmental : Cumene 98-82-8

Protection Act - National Cumyl hydroperoxide 80-15-9

Pollutant Release Inventory Acetophenone 98-86-2

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

Other regulatory information European Union

Water contaminating class : WGK 2 obviously hazardous to water

(Germany) Classification according to AwSV, Annex 1 (5.2)

Seveso III: Directive 2012/18/EU of the H2 ACUTE TOXIC

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** 

E2 ENVIRONMENTAL HAZARDS

E2

Regulation on prevention of major industrial

accidents. Reg number 30702

H2 ACUTE TOXIC

P6b SELF-REACTIVE SUBSTANCES

AND MIXTURES and ORGANIC

**PEROXIDES** 

E2 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: Not applicable

Carcinogenic substances: Not applicable

Mutagenic: Not applicable

Toxic to reproduction: Not applicable

Volatile organic compounds

US. Clean Air Act Section 111 SOCMI Intermediate or Final Volatile Organic Compunds (VOC) - 40 CFR part 60.489 The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI 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.

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.

US. Clean Air Act Section 111 SOCMI Intermediate or Final Volatile Organic Compunds (VOC) - 40 CFR part 60.489 The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

### Other regulatory information Japan **Chemical Substance Control Law**

Priority Assessment Chemical Substance

Chemical name	Number	
Cumene	126	

# 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**

Components	CAS-No.	Component RQ (lbs)
Cumyl hydroperoxide	80-15-9	10 lbs

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

304 EHS RQ.

SARA 311/312 : Organic peroxides

Acute toxicity (any route of exposure)

Specific target organ toxicity (single or repeated exposure)

Skin corrosion or irritation

Serious eye damage or eye irritation

Aspiration hazard

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:

 Cumyl hydroperoxide
 80-15-9
 82 - 86 %

 Cumene
 98-82-8
 7 - 13 %

 Acetophenone
 98-86-2
 0,5 - 1,5 %

### Clean Air Act

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 112 (40 CFR 61):

Cumene 98-82-8 7 - 13 % Acetophenone 98-86-2 0,5 - 1,5 %

This product does not contain any chemicals subject to disclosure and listed under the U.S. Clean Air Act Section 112(r) for Accidental Polyago Provention (40 CEP 68 130 Subpart E)

Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

 Cumyl hydroperoxide
 80-15-9
 70 - 90 %

 Cumene
 98-82-8
 10 - 20 %

 Acetophenone
 98-86-2
 1 - 5 %

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

 Cumyl hydroperoxide
 80-15-9
 82 - 86 %

 Cumene
 98-82-8
 7 - 13 %

 Acetophenone
 98-86-2
 0,5 - 1,5 %

### **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.

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



### WARNING:

This product can expose you to chemicals including Cumene, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

### **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 **BR** Brazil Belgium **CA** Canada **CH** Switzerland CL Chile CO Colombia CR Costa Rica **DE** Germanv DK Denmark EC Ecuador **EU** European Union Finland FR France ES Spain FΙ **GB** United Kingdom Indonesia ID IN India IT Italy JP Japan MX Mexico NL The Netherlands PA Panama **REG WORLD** PE Peru PH Philippines World SE Sweden **SG** Singapore SV El Salvador TH Thailand TR Turkey **UY** Uruguay US USA ۷E Venezuela VN Vietnam

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