Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024

Version: 6.0 Replaced version: 5.0



	SECTION 1: Identification of	of the substance or mixture and of the company/undertaking		
1.1	Product identifier	Muppy Pearl II transparent/rigid Article no.: 93502		
1.2	Relevant identified uses of the sul	Relevant identified uses of the substance or mixture and uses which are not recommended		
1.2.1	Relevant uses medical device:	Medical device - oral vestibule plate		
1.2.2	Uses that are not recommended:	None known		
1.3	Details of the supplier providing the safety data sheet	Dr. Hinz Dental Vertriebsgesellschaft mbH & Co. KG           Friedrich der Große 64           44628 Herne           GERMANY           Phone: + 49 (0) 23 23 / 59 34 20           Fax: + 49 (0) 23 23 / 59 34 29           E-Mail: qm@dhug.de		
1.4	Emergency number	Contact: <b>Dr. P. Hinz</b> Phone: + 49 17 51 83 41 34		

#### **SECTION 2: Possible dangers**

#### 2.1 Classification of the substance or mixture

The material test in accordance with DIN EN ISO/IEC 17025 was carried out by a testing laboratory accredited by Deutsche Akkreditierungsstelle GmbH.

This material test resulted in a bisphenol A value [CAS 80-05-7] of < 0.02 mg/l, which is below the current limit value of 0.04 mg/l.

The test is deemed to have been passed and can continue to be declared as safe for sale.

#### 2.1.1 Classification according to (EC) Regulation 1272/2008 as amended.

#### Not classified

INGREDIENT		Product identification	%	TLV	Classification	
Iron	FE	CAS-Nr. 7439-89-6 EG-Nr. 231-096-4	<90	5 mg/m²		
Chrom	Cr	CAS-Nr. 7440-47-3 EU-Nr. 231-157-5	10 -30	5 mg/m <sup>2</sup>	Not a hazardous substance according to GHS	
Nickel	Ni	CAS-Nr. 7440-02-0 EU-Nr. 231-111-4 Index-Nr.028-002-00-7 028-002-01-4	< 15	1 mg/m²	<b>③</b> (!)	H351, Cat. 2 H372, Cat. 1 H317, Cat. 1 H412, Cat. 3
Manganese	Mn	CAS-Nr. 7439-96-5 EG-Nr. 231-105-1	< 15	1 mg/m²		
Phosphor	Р	CAS-Nr. 7723-14-0	< 0.05	1 mg/m²		
Sulphur	S	CAS-Nr. 7704-34-9	<0.5	5 mg/m <sup>2</sup>		
Silizium	SI	CAS-Nr. 7440-21-3	< 5	5 mg/m <sup>2</sup>		

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024



2.3	Other dangers		This 0.1% toxic	substance	e/mixture does n r that are classif	ot contain components ied as either persistent and very bioaccumulati	, bioaccumulative and	
2.2	Labelling eleme				applicable	No data availab	le	
	Aluminium	AL	7429-90-5		< 3	10 mg/m <sup>2</sup>		
	Соррег	CO	EG-Nr 231-159-6			0.2 mg/m		
	Copper	CU	Index: 027-001-00-9	9	< 5	0.2 mg/m <sup>2</sup>	•	H413, Cat. 4
			EG: 231-158-0	,		mg/m²		H317, Cat. 1
	Kobalt	Со	CAS: 7440-48-4		< 1	0.05		H334, Cat. 1
	Titan	Ti	7440-32-6		< 1	10 mg/m <sup>2</sup>		
			20 1111 201 107 2				according to GHS	
	Wiorybacham	IVIO	EU-Nr.: 231-107-2			10 1116/111	substance	
	Molybdenum	Мо	CAS-Nr.: 7439-98-7		< 5	10 mg/m <sup>2</sup>	Not a hazardous	
	Carbon	С	CAS-Nr. 7440-44-0		< 0.3	55 mg/m <sup>2</sup>		
			EG-Nr. 215-609-9					

	SECTION 3: Comp	oosition / Inform	ation or	n ingredients		
3.1	Chemical characterisation	Polycarbonate, nickel Ferrous alloy with up to 19 % Cr, 17 % Mn, possibly with other elements > 1 %, but not to be marked See also 2.1.1				
		The chemical co	mposition	of stainless steel	is as follow	
		INGREDIENT	•	CAS-NR.	%	TLV
		Iron	FE	7439-89-6	<90	5 mg/m <sup>2</sup>
		Chrom	Cr	7440-47-3 10	10 -30	5 mg/m²
		Nickel	Ni	7440-02-0	< 15	1 mg/m²
		Manganese	Mn	7439-96-5	< 15	1 mg/m²
		Phosphor	Р	7723-14-0	< 0.05	1 mg/m²
		Sulphur	S	7704-34-9	<0.5	5 mg/m <sup>2</sup>
		Silizium	SI	7440-21-3	< 5	5 mg/m <sup>2</sup>
		Carbon	С	7440-44-0	< 0.3	55 mg/m <sup>2</sup>
		Molybdenum	Мо	7439-98-7	< 5	10 mg/m <sup>2</sup>
		Titan	Ti	7440-32-6	< 1	10 mg/m <sup>2</sup>
		Kobalt	Со	7440-48-4	< 1	0.05 mg/m <sup>2</sup>
		Copper	CU	7440-550-8	< 5	0.2 mg/m <sup>2</sup>
		Aluminium	AL	7429-90-5	< 3	10 mg/m <sup>2</sup>
3.1.1	Dangerous ingredients	Bisphenol A The material test by a testing labo This material tes mg/l, which is be	in accord ratory acc t resulted low the c	credited by Deutsch in a bisphenol A vurrent limit value o	I ISO/IEC 17 he Akkrediti value [CAS 8 f 0.04 mg/l.	7025 was carried out erungsstelle GmbH.

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024



The stainless steel wire in the moulds supplied does not normally pose any risk to humans or the environment.

		Section 4: First aid measures		
4.1	Description of the first aid measures	S		
	General notes	No action should be taken that involves personal risk or that has not been adequately trained.		
	Inhalation:	Remove to fresh air. Seek medical attention if symptoms occur.		
	Eye contact:	Immediately flush eye with water. Seek medical attention if symptoms occur.		
	Skin contact:	IF IN CONTACT WITH HOT MELT: Cool immediately with plenty of water. Do not remove product crusts from affected skin areas by force or by using solvents. Consult a doctor immediately for treatment of possible burns and for gentle cleansing of the skin.  The following information refers to handling the product at room temperature. In case of contact with skin, wash thoroughly with plenty of soap and water.		
	Ingestion:	Do NOT induce vomiting if swallowed. Administer a glass of water. Seek medical attention.		
4.2	Most important symptoms and effects, both acute and delayed:	No information available.		
4.3	Indications for immediate medical help or special treatment			
	Dangers:	This product is not expected to be harmful under normal use and proper personal hygiene.		
	Treatment:	Do NOT induce vomiting if swallowed. Administer a glass of water.		

	SECTION 5: Fire-fighting measures		
5.1	General fire hazards	Fire residues and contaminated extinguishing water must be disposed of in	
		accordance with local official regulations.	

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024



	Extinguishing agent Suitable extinguishing media	Water spray, extinguishing powder, carbon dioxide (CO2), foam, dry extinguishing agent
	Unsuitable extinguishing media:	Avoid direct water jet; this will disperse and spread the fire
5.2	Special hazards arising from the substance or mixture:	Fire produces carbon dioxide, carbon monoxide, nitrogen oxides and traces of hydrogen cyanide (hydrocyanic acid). Do not inhale explosion and fire gases.
5.3	Advice for firefighters Advice for firefighters:	Respiratory protection with independent air supply required for fire fighting.  Do not allow contaminated extinguishing water to enter the ground, groundwater or bodies of water.
	Special protective equipment for fire fighting:	Wear self-contained breathing apparatus and protective clothing. Do not allow runoff from firefighting materials, even in diluted form, to reach bodies of water, sewers, or drinking water reservoirs. Use ordinary firefighting measures; consider hazards from other materials involved.

	SECTION 6: Accidental release measures			
6.1	Personal precautions, protective equipment and emergency procedures:	Remove all sources of ignition. Wear personal protective equipment.		
6.2	Environmental protection measures:	Do not allow the runoff to enter the sewer system, waterways or soil		
6.3	Methods and material for retention and cleaning:	Wipe up spilled material and take to a safe place. Caution: Contaminated surfaces may be slippery.		
6.4	Reference to other sections:	Caution: Contaminated surfaces may be slippery. Do not allow runoff to reach drains, sewers or bodies of water. For personal protective equipment see section 8 of SDS.		

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Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024



	Section 7	7: Handling and storage:
7.1	Protective measures for safe handling:	Under the recommended processing conditions, small quantities of emitters, essentially residual monomers and residual solvents, may be released. Ensure that the limit values specified in Section 8 are complied with by providing adequate ventilation or extraction at the workplace.  Provide effective extraction of dusts during mechanical processing. Keep away from food and beverages. Wash hands and apply skin protection ointment before breaks and at the end of work. Change contaminated clothing.
	Notes on fire and explosion protection:	No special storage conditions required.
7.2	Conditions for safe storage taking into account incompatibilities:	No special storage conditions required.
	Storage stability:	No information available.
	Storage class:	Storage class (TRGS 510) : 11: Combustible solids
7.3	Specific end uses:	No information available.

	SECTION 8: Exposur	e controls/personal protective equipment			
8.1	Parameters to be monitored Occupationa exposure limit values	When processing this product, especially in the thermal process, the regulations for the substances listed below must be observed. According to our experience, the limit values quoted below can be safely complied with if effective devices for ventilation and extraction are used at the discharge points of any vapors that may arise.			
	Biological limit values	See Subsection 16 Table 8.1			
8.2	Exposure controls Suitable engineering controls:	Eye showers and emergency showers must be available in the workplace. Provide adequate general and local exhaust ventilation system.			
	Individual protective measures, for example personal protective equipment				
	General information:	Eye wash bottle with pure water. Do not eat, drink or smoke while working. Wash hands after handling			
	Eye/face protection:	Wear safety goggles/face protection.			
	Skin protection Hand protection:	Geeignete Materialien für Schutzhandschuhe; EN 374: Polyvinylchlorid - PV Dicke >=0,5mm			
		Kontaminierte und/oder beschädigte Handschuhe sind zu wechseln.			
	Other:	Wear suitable protective clothing and goggles/face protection when working.			
	Respiratory protection:	In case of dust generation, use filter unit with filter type particle filter P1 according to EN 150			

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024



Hygiene measures:	Observe recognized industrial hygiene measures. Do not eat, drink or smoke
	while working. Maintain good personal hygiene. Thoroughly clean hands and
	contaminated work areas with soap and water before leaving the workplace.
	Avoid contact with skin and eyes.
Limitation and monitoring of	There are no data available.
environmental exposure:	

	SECTION 9: Physical	and chemical properties					
9.1	Information on the basic physical and chemical properties						
	Parameter	Wert					
	State of aggregation	solid at 20 °C at 1,013 hPa					
	Colour	Transparent					
	Smell	Odorless					
	Melting point/freezing point	Softening point: 130 - 160 °C					
	Boiling point or initial boiling point and boiling range	not determined					
	Flammability	not determined					
	Lower explosion limit upper explosion limit	Not applicable					
	Flash point	not determined					
	Ignition temperature	> 450 °C					
	Decomposition temperature	>= 380 °C					
	pH value	Not applicable					
	Kinematic viscosity	Not applicable					
	Solubility	practically insoluble					
	Partition coefficient n-octanol/water (log value)	not determined					
	Vapour pressure	Not applicable					
	Density and/or specific gravity	ca. 1,2 - 1,4 g/cm					
	Relative vapour density	not determined					
	Particle properties	not determined					
9.2.	Other information Nickel Iron alloy Form: solid Color: silver-gray, metallic Odor: odorless pH: not applicable Boiling point: not applicable Melting point: 1400 - 1550°C (depending on steel grade Flash point: not applicable Flammability: not applicable Ignition temperature: not applicable Spontaneous ignitic Oxidizing properties: not applicablePhysical and chemic	on: not applicable					

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024



Parameter	Wert
Aggregatzustand / Form	fest
Farbe	grau metallisch
Geruch	Geruchlos
Schmelzpunkt/Gefrierpunkt	1300-1500 °C
Siedepunkt oder Siedebeginn und Siedebereich	Nicht anwendbar
Entzündbarkeit	Nicht anwendbar
Untere Explosionsgrenze obere Explosionsgrenze	Nicht anwendbar
Flammpunkt	Nicht anwendbar
Zündtemperatur	Nicht anwendbar
Zersetzungstemperatur	Nicht anwendbar
oH-Wert	Nicht anwendbar
Kinematische Viskosität	Nicht anwendbar
Löslichkeit	Nicht löslich in Wasser
Verteilungskoeffizient n- Oktanol/Wasser (log-Wert)	Nicht anwendbar
Dampfdruck	Nicht anwendbar
Dichte und/oder relative Dichte	7,9-8,0 g/cm <sup>3</sup>
Relative Dampfdichte	Nicht anwendbar
Partikeleigenschaften	Nicht anwendbar

	SECTION 10: Stability and reactivity					
10.1	Reactivity	No information available				
10.2	Chemical stability	In the event of thermal decomposition, as occurs in the event of fire or due to overheating in the case of improper processing, for example, harmful gases and vapors may be formed.				
10.3	Possibility of hazardous reactions	No dangerous reactions observed.				
10.4	Conditions to avoid	No information available				
10.5	Incompatible materials	No information available				
10.6	Decomposition products	During carbonization or incomplete combustion, toxic gas mixtures containing mainly CO and CO2 develop.  Under the recommended processing conditions, small amounts of emitters may be released.				
		When processing this product, especially in the thermal process, the regulations for the substances listed below must be observed. Phenol; Carbolic acid; Monohydroxybenzene; Phenylalcohol				
		INDEX No. 604-001-00-2  CAS No.: 108-95-2				

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Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024

Version: 6.0 Replaced version: 5.0



Classification (1272/2008/EC): Acute Tox. 3 Oral H301 Acute Tox. 3 Inhalative H331 Acute Tox. 3 Dermal H311 Skin Corr. 1B H314 Eye Dam. 1 H318 Muta. 2 H341 STOT RE 2 H373 Aquatic Chronic 2 H411

Chlorobenzene

INDEX No. 602-033-00-1

CAS No.: 108-90-7

Classification (1272/2008/EC): Flam. Liq. 3 H226 Acute Tox. 4 Inhalative H332 Skin Irrit. 2 H315 Aquatic Chronic 2 H411

4-tert-butylphenol

INDEX No. 604-090-00-8

CAS No.: 98-54-4

Classification (1272/2008/EC): Skin Irrit. 2 H315 Eye Dam. 1 H318 Repr. 2

H361f Aquatic Chronic 1 H410

Bisphenol A; 4,4'-isopropylidenediphenol.

CAS No.: 80-05-7

Classification (1272/2008/EC): Repr. 1B H360F STOT SE 3 Inhalative H335 Eye Dam. 1 H318 Skin Sens. 1 H317 Aquatic Chronic 2 H418

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Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024

Version: 6.0 Replaced version: 5.0



	SECTION 11: Toxicological data						
11.1	Information on hazard classes within the meaning of Regulation (EC) No 1272/2008						
		Toxicological studies on the product are not available.					
	acute toxicity	The stainless steel contains nickel, which is classified in EC Directive 67/548/EEC as a carcinogenic substance (category 3, i.e. of concern to humans but the available information is not sufficient for a satisfactory assessment) by inhalation or ingestion. The conventions of the Preparations Directive 88/379/EEC stipulate that all mixtures, solutions and alloys containing at least 1 la nickel must be classified in the same way by default. To our knowledge, however, neither epidemiological studies nor animal experiments have revealed any carcinogenic effects from contact with stainless steel. Many years of experience with stainless steel in a wide variety of applications have shown that these highly resistant materials are ideally suited where hygiene is of primary concern. Nickel is also classified as a skin sensitiser, with prolonged intimate contact with the skin of some people (e.g. when wearing jewellery).  The products are in solid form and cannot be inhaled or ingested, so they do not pose a toxic hazard (see also section 3, Identification of hazards).  During machining, flame cutting or welding, stainless steel dust or fume containing oxides of its components may be formed. Breathing excessive concentrations in the air over a long period of time can have long-term health effects, particularly on the lungs. However, studies of workers exposed to nickel powder, dust and fumes generated during the production of nickel alloys and stainless steels have not shown any evidence of a respiratory cancer risk.					
	Corrosive/irritant effect on the skin	No data available.					
	Serious eye damage/irritation	No data available.					
	Sensitisation of the respiratory tract/skin	No data available.					
	Germ cell mutagenicity	No data available.					
	Carcinogenicity	No data available.					
	Reproductive toxicity	According to our experience and information, the product does not cause any adverse health effects when handled properly.					
	Specific target organ toxicity at single exposure	No data available.					
	Specific target organ toxicity in case of repeated exposure	No data available.					
	Aspiration hazard	No data available.					
11.2	Information on other hazards	No data available.					
11.2.1	Endocrine disrupting properties	No data available.					
11.2.2	Other information	No data available.					

#### **SECTION 12. Environmental information**

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024

Version: 6.0 Replaced version: 5.0



12.1	Toxicity	No data available.
12.2	Persistence and degradability	No data available.
12.3	Bioaccumulative potential	No data available.
12.4	Mobility in soil	The product is practically insoluble in water. Due to its consistency and insolubility in water, no ecological problems are expected if handled properly. The product is not easily biodegradable
12.5	Results of the PBT and vPvB assessment	There are no data available
12.6	Endocrine disrupting properties	This substance/mixture fulfils the PBT criteria of REACH regulation, annex XIII.  There are no data available
12.7	Other adverse effects	There are no data available

	SECTION 13: Disposal instructions							
13.1	Waste treatment process							
	General information	Disposal in compliance with all applicable international, national and local laws, regulations and statutes.						
		For disposal within the EU, the respective valid waste code according to the European Waste Catalogue (EWC) must be used.						
	Disposal methods	Emptied packaging can be handed over for recycling after residual emptying (free-flowing, spatula-clean, drip-free) at the acceptance points of the existing take-back systems of the chemical industry. Recycling must be carried out in accordance with national legislation and environmental protection regulations. The product is suitable for mechanical recycling. After appropriate treatment, it can be remelted and reprocessed into new molded parts. Voraussetzung für ein werkstoffliches Recycling ist materialspezifische Erfassung und sortenreine Verwertung.						

	SECTION 14: Transport information					
14.1	ADR	Not dangerous goods				
14.2	ADN	Not dangerous goods				
14.3	RID	Not dangerous goods				
14.4	IMDG	Not dangerous goods				
14.5	IATA	Not dangerous goods				
14.6	Special precautions for the user:	Not dangerous goods				
14.7	Carriage in bulk in accordance with Annex II of the MARPOL Convention and the IBC Code:	Not dangerous goods				

#### **SECTION 15: Legislation**

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024



15.1	Safety, health and environmental regulations/specific legislation for the substance or mixture:							
	EU regulations							
	Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex I, Controlled substances:	none						
	Regulation (EU) 2019/1021 on persistent organic pollutants (new edition), as amended:	none						
	Regulation (EC) No 649/2012 on the export and import of dangerous chemicals:	none						
	Regulation (EC) No 1907/2006, REACH Annex XIV List of substances subject to authorisation, as amended:	none						
	EU. REACH Candidate List of Substances of Very High Concern (SVHC) for authorisation:	none						
	Regulation (EC) No 1907/2006 Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles:	none						
	Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work:	none						
	Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:							
	Directive 2012/18/EU (Seveso III) on the control of major-accident hazards involving dangerous substances:							
	REGULATION (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register, ANNEX II: Pollutants	none						
	Directive 98/24/EU on the protection of workers from the risks related to chemical agents at work:	none						
	National regulations							
	Water hazard class	nw not hazardous to water Identification number according to AwSV: 773						
	Reference to Technical Rules for Hazardous Substances (TRGS)	none						
	VOC Directive (1999/13/EC) and the Decopaint Directive (2004/42/EC)	none						
	Other regulations	none						
15.2	Chemical safety assessment	No chemical safety assessmen has been carried out for this substance/mixture (or its components).						

	SECTION 16: Other information					
16.1	Information on the revision	Not relevant.				
	Important literature references and data sources:	There are no data available.				

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024

Version: 6.0 Replaced version: 5.0



Training information:	There are no data available.
Disclaimer:	More information  To the best of our knowledge, the information in this safety data sheet corresponds to our knowledge at the time of revision. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transportation and disposal. The information is not transferable to other products. Insofar as the product named in this safety data sheet is mixed, blended or processed with other materials, or is subjected to processing, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.

8.1 Biological limits

Stoff	CAS-Nr.	Basis	Туре	Value	Peak limiting value	Notes
Phenol; Carbolsäure; Monohydroxybenzol; Phenylalcohol	108-95-2	EU ELV	TWA	2 ppm 8 mg/m3		indicative
Phenol; Carbolsäure; Monohydroxybenzol; Phenylalcohol	108-95-2	EU ELV				Skin resoption possible
Phenol; Carbolsäure; Monohydroxybenzol; Phenylalcohol	108-95-2	EU ELV	STEL	4ppm 16 mg/m3		indicative
Phenol; Carbolsäure; Monohydroxybenzol; Phenylalcohol	108-95-2	TRGS 900				Registered
Phenol; Carbolsäure; Monohydroxybenzol; Phenylalcohol	108-95-2	TRGS 900				Skin resoption possible
Phenol; Carbolsäure; Monohydroxybenzol; Phenylalcohol	108-95-2	TRGS 900		2ppm 8 mg/ m3	2	
Phenol; Carbolsäure; Monohydroxybenzol; Phenylalcohol	108-95-2	TRGS 900	Short- term overru n			Category II: Resorptive substances
Chlorbenzol	108-90-7	TRGS 900				Registered
Chlorbenzol	108-90-7	TRGS 900		5 ppm 23mg/m3	2	Y
Chlorbenzol	108-90-7	EU ELV	TWA	5 ppm 23mg/m3		indicative
Chlorbenzol	108-90-7	EU ELV	STEL	15 ppm 70 mg/m3		indicative
Chlorbenzol	108-90-7	TRGS 900	Short- term overru n			Category II: Resorptive substances
4-tert-Butylphenol	98-54-4	TRGS 900				Registered
4-tert-Butylphenol	98-54-4	TRGS 900		0,08 ppm 0,5 mg/m3	2	
4-tert-Butylphenol	98-54-4	TRGS 900				Skin resoption possible

Complies with Regulation (EC) No 1907/2006 (REACH), Annex II, amended according to Regulation (EU) No 2020/878

Muppy Pearl II transparent/rigid

Article no.: No. 93502

Revised on: 14.05.2024



4-tert-Butylphenol	98-54-4	TRGS 900	Short- term overru n			
Bisphenol A; 4,4`- Isopropylidendiphenol	80-05-7	TRGS 900				Registered
Bisphenol A; 4,4'- Isopropylidendiphenol	80-05-7	TRGS 900	Short- term overru n			Category I
Bisphenol A; 4,4`- Isopropylidendiphenol	80-05-7	TRGS 900		5mg/m3		Υ
Bisphenol A; 4,4`- Isopropylidendiphenol	80-05-7	EU ELV	TWA	2 mg/m3		indicative
General dust limit		TRGS 900		10 mg/m3	2	Inhalable fraction
General dust limit		TRGS 900		3 mg/m3	2	alveolengägnig fraction
General dust limit		TRGS 900	Short- term overru n			Category II: Resorptive substances