



Material Safety Data Sheet

<p>Name of the Product : MacConkey Agar RS Code No. : PM2702</p> <p>Section 1 : Chemical Identification</p> <p>Code No. : PM2702 Name of the Product : MacConkey Agar RS Produced by : Central Drug House Pvt. Ltd. Address : 7/28 Vardaan House, Darya Ganj, New Delhi (INDIA) Tel. No. : 00 91 11 49404040</p>																			
Section 2	Hazards Identification																		
	<p>2.1 Classification of the substance or mixture CLP Classification-Regulation (EC) No. 1272/2008[EU-GHS/CLP]</p> <p>This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.</p> <p>2.2 Label elements Labeling according to Regulation (EC) No.1272/2008</p> <p><i>No required</i></p> <p>2.3 Other Hazards</p> <p>Results of PBT and vPvB assessment</p> <p>Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.</p> <p>Endocrine disrupting properties</p> <p>Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.</p>																		
Section 3	Composition/Information On Ingredients																		
	<p>3.1 Substances</p> <p>Not relevant (mixture)</p> <p>3.2 Mixture</p> <table border="1"><thead><tr><th>Name of substance</th><th>Identifier</th><th>Wt%</th><th>Classification acc. to GHS</th></tr></thead><tbody><tr><td>Crystal violet</td><td>CAS No 548-62-9 EC No 208-953-6 Index No 612-205-00-8</td><td>< 1</td><td>Acute Tox. 4 / H302 Eye Dam. 1 / H318 Carc. 1B / H350 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410</td></tr></tbody></table> <table border="1"><thead><tr><th>Name of substance</th><th>Specific Conc. Limits</th><th>M-Factors</th><th>ATE</th><th>Exposure route</th></tr></thead><tbody><tr><td>Crystal violet</td><td>--</td><td>--</td><td>420 mg/kg</td><td>oral</td></tr></tbody></table>	Name of substance	Identifier	Wt%	Classification acc. to GHS	Crystal violet	CAS No 548-62-9 EC No 208-953-6 Index No 612-205-00-8	< 1	Acute Tox. 4 / H302 Eye Dam. 1 / H318 Carc. 1B / H350 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410	Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route	Crystal violet	--	--	420 mg/kg	oral
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Section 4	First - Aid Measures
	<p>4.1 Description of first aid measures</p> <p>General advice</p> <p><i>Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.</i></p> <p>If inhaled</p> <p><i>If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.</i></p> <p>In case of skin contact</p> <p><i>Wash off with soap and plenty of water. Consult a physician.</i></p> <p>In case of eye contactas</p> <p><i>Rinse immediately with plenty of water for at least 15 minutes. Consult a physician.</i></p> <p>If swallowed</p> <p><i>Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.</i></p> <p>4.2 Most important symptoms and effects, both acute and delayed</p> <p>No data available.</p> <p>4.3 Indication of immediate medical attention and special treatment needed</p> <p>No data available</p>
Section 5	Fire Fighting Measures
	<p>5.1 Extinguishing media</p> <p>Suitable extinguishing media</p> <p>Water, Foam, ABC-powder</p> <p>Unsuitable extinguishing media</p> <p>Water jet</p> <p>5.2 Special hazards arising from the substance or mixture</p> <p>Carbon oxides, Hydrogen chloride gas, Sodium oxides.</p> <p>5.3 Advice for firefighters</p> <p>In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.</p> <p>5.4 Further information</p> <p>No data available</p>
Section 6	Accidental Release Measures
	<p>6.1 Personal precautions, protective equipment and emergency procedures</p> <p>For non-emergency personnel</p> <p>Remove persons to safety.</p> <p>For emergency responders</p> <p>Wear breathing apparatus if exposed to vapours/dust/spray/gases.</p> <p>6.2 Environmental precautions</p> <p>Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.</p> <p>6.3 Methods and materials for containment and cleaning up</p> <p>Advice on how to contain a spill</p> <p>Covering of drains, Take up mechanically</p> <p>Advice on how to clean up a spill</p> <p>Take up mechanically.</p> <p>Other information relating to spills and releases</p> <p>Place in appropriate containers for disposal. Ventilate affected area.</p> <p>6.4 Reference to other sections</p> <p>Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.</p>



Section 7	Handling and Storage																																																																							
	<p>7.1 Precautions for safe handling</p> <p>Recommendations</p> <ul style="list-style-type: none">- Measures to prevent fire as well as aerosol and dust generation <p>Use local and general ventilation. Take precautionary measures against static discharge. Use only in well-ventilated areas. Ground/bond container and receiving equipment.</p> <ul style="list-style-type: none">- Specific notes/details <p>Dust deposits may accumulate on all deposition surfaces in a technical room. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.</p> <p>Advice on general occupational hygiene</p> <p>Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals.</p> <p>Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.</p> <p>7.2 Conditions for safe storage, including any incompatibilities</p> <p>Managing of associated risks</p> <ul style="list-style-type: none">- Explosive atmospheres <p>Removal of dust deposits.</p> <ul style="list-style-type: none">- Ventilation requirements <p>Use local and general ventilation.</p> <ul style="list-style-type: none">- Specific designs for storage rooms or vessels <p>Recommended Storage Temperature : Store between 20 – 30 °C</p> <p>7.3 Specific end uses</p> <p>See section 16 for a general overview.</p>																																																																							
Section 8	Exposure Controls / Personal Protection																																																																							
	<p>8.1 Control parameters</p> <table border="1"><thead><tr><th colspan="11">Occupational exposure limit values (Workplace Exposure Limits)</th></tr><tr><th>Country</th><th>Name of agent</th><th>CAS No</th><th>Identifier</th><th>TWA [ppm]</th><th>TWA [mg/ms]</th><th>STEL [ppm]</th><th>STEL [mg/ms]</th><th>Ceiling-C [ppm]</th><th>Ceiling-C [mg/ms]</th><th>Notation</th><th>Source</th></tr></thead><tbody><tr><td>DE</td><td>dust</td><td></td><td>MAK</td><td></td><td>4</td><td></td><td></td><td></td><td></td><td>i</td><td>DFG</td></tr><tr><td>DE</td><td>dust</td><td></td><td>MAK</td><td></td><td>0,3</td><td></td><td>2,4</td><td></td><td></td><td>r</td><td>DFG</td></tr><tr><td>DE</td><td>dust</td><td></td><td>AGW</td><td></td><td>10</td><td></td><td>20</td><td></td><td></td><td>Y, i</td><td>TRGS 900</td></tr><tr><td>DE</td><td>dust</td><td></td><td>AGW</td><td></td><td>1,25</td><td></td><td>2,5</td><td></td><td></td><td>Y, r</td><td>TRGS 900</td></tr></tbody></table> <p>Notation</p> <p>Ceiling-C ceiling value is a limit value above which exposure should not occur</p> <p>i inhalable fraction</p> <p>r respirable fraction</p> <p>STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)</p> <p>TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours</p> <p>time-weighted average (unless otherwise specified)</p> <p>Y a risk of developmental toxicity does not need to be expected if the occupational exposure limit value and the biological limit value (BGW) are adhered to</p>	Occupational exposure limit values (Workplace Exposure Limits)											Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/ms]	STEL [ppm]	STEL [mg/ms]	Ceiling-C [ppm]	Ceiling-C [mg/ms]	Notation	Source	DE	dust		MAK		4					i	DFG	DE	dust		MAK		0,3		2,4			r	DFG	DE	dust		AGW		10		20			Y, i	TRGS 900	DE	dust		AGW		1,25		2,5			Y, r	TRGS 900
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	<p>8.2 Exposure controls</p> <p>Appropriate engineering controls</p> <p>Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the products.</p> <p>Personal protective equipment</p> <p>Hygiene measure</p> <p>Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with the product.</p> <p>Eye/face protection</p> <p>Tightly fitting safety goggles; Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).</p> <p>Skin protection</p> <p>Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.</p> <p>Body protection</p> <p>Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.</p> <p>Respiratory protection</p> <p>Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).</p> <p>Environment exposure controls</p> <p>Do not empty into drains.</p>																																						
Section 9	<p>Physical and Chemical Properties</p> <p>9.1 Information on basic physical and chemical properties</p> <table><tbody><tr><td>Physical state</td><td>Solid</td></tr><tr><td>Colour</td><td>Sterile medium in 90mm disposable petri</td></tr><tr><td></td><td>Plates - Red with purplish tinge coloured medium</td></tr><tr><td>Odour</td><td>Characteristic</td></tr><tr><td>Melting/freezing point</td><td>Not determined</td></tr><tr><td>Initial boiling point and boiling range</td><td>Not determined</td></tr><tr><td>Flammability</td><td>Non-combustible</td></tr><tr><td>Lower and upper explosion limit</td><td>Not determined</td></tr><tr><td>Flash point</td><td>Not applicable</td></tr><tr><td>Autoignition Temperature</td><td>Not determined</td></tr><tr><td>Decomposition temperature</td><td>Not relevant</td></tr><tr><td>pH (value)</td><td>6.9 – 7.3</td></tr><tr><td>Kinematic viscosity</td><td>Not relevant</td></tr><tr><td>Solubility(ies)</td><td>Soluble in water</td></tr><tr><td>Partition coefficient: n-octanol/water</td><td>No data available</td></tr><tr><td>Vapour pressure</td><td>Not determined</td></tr><tr><td>Density</td><td>Not determined</td></tr><tr><td>Relative density</td><td>No data available</td></tr><tr><td>Particle characteristics</td><td>No data available</td></tr></tbody></table> <p>9.2 Other safety information</p> <p>Information with regard to physical hazard classes</p> <p>hazard classes acc. to GHS (physical hazards): not relevant</p> <p>Other safety characteristics</p> <p>there is no additional information</p>	Physical state	Solid	Colour	Sterile medium in 90mm disposable petri		Plates - Red with purplish tinge coloured medium	Odour	Characteristic	Melting/freezing point	Not determined	Initial boiling point and boiling range	Not determined	Flammability	Non-combustible	Lower and upper explosion limit	Not determined	Flash point	Not applicable	Autoignition Temperature	Not determined	Decomposition temperature	Not relevant	pH (value)	6.9 – 7.3	Kinematic viscosity	Not relevant	Solubility(ies)	Soluble in water	Partition coefficient: n-octanol/water	No data available	Vapour pressure	Not determined	Density	Not determined	Relative density	No data available	Particle characteristics	No data available
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Section 10	Stability and Reactivity 10.1 Reactivity Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials". 10.2 Chemical stability The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure. 10.3 Possibility of hazardous reactions No known hazardous reactions. 10.4 Conditions to avoid There are no specific conditions known which have to be avoided. Hints to prevent fire or explosion The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion. 10.5 Incompatible materials No data available 10.6 Hazardous decomposition products Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.															
Section 11	Toxicological Information 11.1 Information on toxicological effects Test data are not available for the complete mixture. Classification procedure The method for classification of the mixture is based on ingredients of the mixture (additivity formula). Classification according to GHS (1272/2008/EC, CLP) This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC. Acute toxicity Shall not be classified as acutely toxic. <table border="1"><thead><tr><th colspan="5">Acute toxicity estimate (ATE) of components of the mixture</th></tr><tr><th>Name of substance</th><th>CAS No</th><th>M-Factors</th><th>Exposure route</th><th>ATE</th></tr></thead><tbody><tr><td>Crystal violet</td><td>548-62-9</td><td>--</td><td>oral</td><td>420 mg/kg</td></tr></tbody></table> Skin corrosion/irritation Shall not be classified as corrosive/irritant to skin. Serious eye damage/eye irritation Shall not be classified as seriously damaging to the eye or eye irritant. Respiratory or skin sensitisation Shall not be classified as a respiratory or skin sensitiser. Germ cell mutagenicity Shall not be classified as germ cell mutagenic. Carcinogenicity Shall not be classified as carcinogenic. Reproductive toxicity Shall not be classified as a reproductive toxicant. Specific target organ toxicity- single exposure Shall not be classified as a specific target organ toxicant (single exposure). Specific target organ toxicity- repeated exposure Shall not be classified as a specific target organ toxicant (repeated exposure). Aspiration hazard Shall not be classified as presenting an aspiration hazard.	Acute toxicity estimate (ATE) of components of the mixture					Name of substance	CAS No	M-Factors	Exposure route	ATE	Crystal violet	548-62-9	--	oral	420 mg/kg
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	<p>11.2 Information on other hazards There is no additional information.</p>
Section 12	<p>Ecological Information</p> <p>12.1 Toxicity Acc. to 1272/2008/EC: Shall not be classified as hazardous to the aquatic environment. Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV): WGK 1, slightly hazardous to water (Germany)</p> <p>Biodegradation The relevant substances of the mixture are readily biodegradable.</p> <p>12.2 Persistence and degradability No data available</p> <p>12.3 Bioaccumulative potential No data available</p> <p>12.4 Mobility in soil No data available</p> <p>12.5 PBT and vPvB assessment According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.</p> <p>12.6 Endocrine disrupting properties Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.</p> <p>12.7 Other adverse effects No data available</p>
Section 13	<p>Disposal Considerations</p> <p>13.1 Waste treatments methods Sewage disposal-relevant information Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets. Waste treatment of containers/packagings Use appropriate container to avoid environmental contamination. Completely emptied packages can be recycled.</p> <p>Remarks Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.</p>
Section 14	<p>Transport Information</p> <p>14.1 UN-No ADNR: ADR: IATA_C: IATA_P: IMDG: RID:</p> <p>14.2 UN proper shipping name ADNR : Not dangerous good ADR : Not dangerous good IATA_C : Not dangerous good IATA_P : Not dangerous good IMDG : Not dangerous good RID : Not dangerous good</p> <p>14.3 Transport hazard class (es) ADNR: ADR: IATA_C: IATA_P: IMDG: RID:</p> <p>14.4 Packaging group ADNR: ADR: IATA_C: IATA_P: IMDG: RID:</p> <p>14.5 Environmental hazards ADNR : No ADR : No IMDG : Marine pollutant No IATA_C : No IATA_P : No RID : No</p> <p>14.6 Special precautions for use No data available</p>



Section 15	Regulatory Information																				
	<p>This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.</p> <p>15.1 Safety health and environment regulations/legislation specific for the substance or mixture</p> <p>Relevant provisions of the European Union (EU)</p> <p>Restrictions according to REACH, Annex XVII</p> <p>Dangerous substances with restrictions (REACH, Annex XVII)</p> <table border="1"><thead><tr><th>Name of substance</th><th>Name acc. to inventory</th><th>CAS No</th><th>Restriction</th><th>No</th></tr></thead><tbody><tr><td>Crystal violet</td><td>[4-[4,4'-bis(dimethylamino) benzhydrylidene] cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)</td><td>548-62-9</td><td>R72 R72_50mg</td><td>72</td></tr><tr><td>Crystal violet</td><td>this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC</td><td></td><td>R3</td><td>3</td></tr><tr><td>Crystal violet</td><td>carcinogenic</td><td></td><td>R28-30</td><td>28</td></tr></tbody></table> <p>Legend</p> <p>R28-30 1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none">- as substances,- as constituents of other substances, or,- in mixtures, <p>for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:</p> <ul style="list-style-type: none">- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,- the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. <p>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling</p> <p>of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p>'Restricted to professional users'.</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <ul style="list-style-type: none">(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;(b) cosmetic products as defined by Directive 76/768/EEC;(c) the following fuels and oil products: <ul style="list-style-type: none">- motor fuels which are covered by Directive 98/70/EC,- mineral oil products intended for use as fuel in mobile or fixed combustion plants,- fuels sold in closed systems (e.g. liquid gas bottles); <ul style="list-style-type: none">(d) artists' paints covered by Regulation (EC) No 1272/2008;(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date;(f) devices covered by Regulation (EU) 2017/745. <p>R3 1. Shall not be used in:</p> <ul style="list-style-type: none">- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,- tricks and jokes,- games for one or more participants, or any article intended to be used as such, even with ornamental aspects, <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p> <p>3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both,</p> <p>if they:</p> <ul style="list-style-type: none">— can be used as fuel in decorative oil lamps for supply to the general public, and— present an aspiration hazard and are labelled with H304. <p>4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).</p>	Name of substance	Name acc. to inventory	CAS No	Restriction	No	Crystal violet	[4-[4,4'-bis(dimethylamino) benzhydrylidene] cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)	548-62-9	R72 R72_50mg	72	Crystal violet	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3	Crystal violet	carcinogenic		R28-30	28
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5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:

(a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows:

“Keep lamps filled with this liquid out of the reach of children”; and, by 1 December 2010, “Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage”;

(b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: ‘Just a sip of grill lighter fluid may lead to life threatening lung damage’;

(c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.’;

Legend

R72

R72_50

mg

1. Shall not be placed on the market after 1 November 2020 in any of the following:

(a) clothing or related accessories;

(b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;

(c) footwear;

if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present

in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix

12.

2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery,

the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter.

3. Paragraph 1 shall not apply to:

(a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural

leather, fur or hide;

(b) non-textile fasteners and non-textile decorative attachments;

(c) second-hand clothing, related accessories, textiles other than clothing or footwear

(d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners.

4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament

and of the Council (**).

5. Paragraph 1(b) shall not apply to disposable textiles. ‘Disposable textiles’ means textiles that are designed to be used only

once or for a limited time and are not intended for subsequent use for the same or a similar purpose.

6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.

7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.

(*) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment

and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

(**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

Appendix 12 (maximum concentration limits by weight in homogeneous materials): 50 mg/kg

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list



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Substance of Very High Concern (SVHC)			
Name acc. to inventory	CAS No	Listed in	Remarks
[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)	548-62-9	Candidate list	Carc. A57a

Legend

candidate list Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV
Carc. A57a Carcinogenic (article 57a)

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

Water Framework Directive (WFD)

List of pollutants (WFD)			
Name of substance	CAS No	Listed in	Remarks
Crystal violet		a)	

Legend

A) Indicative list of the main pollutants

Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

National regulations (Germany)

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV)

Wassergefährdungsklasse, WGK

(water hazard class)

3 highly hazardous to water

Storage of hazardous substances in non-stationary containers (TRGS 510) (Germany)

Storage class (LGK)

13 (non-combustible solids)

National inventories

Country	Inventory	Status
EU	REACH Reg.	all ingredients are listed
US	TSCA	all ingredients are listed (ACTIVE)

Legend

REACH Reg. REACH registered substances

TSCA Toxic Substance Control Act

15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.



Material Safety Data Sheet

Section 16	Other Information
	<p>Further Information</p> <p>The information contained in this data sheet represents the best information currently available to us. However, no warranty is made with respect to its completeness and we assume no liability resulting from its use. The information is offered solely for user's obligation to investigate and determine the suitability of the information for their particular purpose.</p>