

**SAFETY DATA SHEET**  
**According to Regulation (EC) No. 1907/2006**

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Trade name:	<b>FAST GREEN F.C.F. CONTRAST REAGENT</b>			
Product code:	FGKR-OT-X**	Date of compilation:	15 March 2017	Version: 2

<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>		
<b>1.1. Product identifier</b>		
Trade name:	FAST GREEN F.C.F. CONTRAST REAGENT	
Chemical name:	-	
Catalogue number:	FGKR-OT-X	
<b>1.2. Relevant identified uses of the substance or mixture and uses advised against</b>		
Uses:	For use in histology	
Uses advised against:	Only the identified uses are advised.	
Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.	
<b>1.3. Details of the supplier of the safety data sheet</b>		
Supplier:	BioGnost Ltd.	
Address:	Medjugorska 59, Zagreb	
Telephone number:	+385 1 2409997	
Telefax:	+385 1 2404039	
e-mail of competent person:	vladimir.ramljak@biognost.hr	
National contact:	Vladimir Ramljak	
<b>1.4. Emergency telephone numbers</b>		
National Protection and Rescue Directorate:	112	
Medical information:	+385 1 2348 342	
Other information:	-	

<b>SECTION 2. Hazards identification</b>		
<b>2.1. Classification of the substance or mixture</b>		
<b>2.1.1. Classification according to Regulation (EC) No 1272/2008 (CLP)</b>		
Hazard class and category code:	Hazard statements*:	
Not identified as hazardous substance.	-	
<b>2.1.2. Additional information</b>		
-		
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
<b>2.2. Label elements</b>		
Product identification:	FAST GREEN F.C.F. CONTRAST REAGENT	
Identification number:	-	
Authorisation number:	-	
Hazard pictograms:	-	
Signal word:	-	
Hazard statement:	-	

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Precautionary statements:	-
Supplemental hazard information (EU):	-
<b>2.3. Other hazards</b>	
-	

**SECTION 3. Composition/information on ingredients**

CAS/EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
2353-45-9/ 219-091-5/ -	-	< 0.5	dihydrogen (ethyl)[4-[4-[ethyl(3-sulphonatobenzyl)amino](4-hydroxy-2-sulphonatobenzhydrylidene)cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)ammonium, disodium salt	Skin Irr. 2; H315 Eye Irr. 2; H319 STOT SE 3; H335

**SECTION 4. First aid measures**

<b>4.1. Description of first aid measures</b>	
General notes:	-
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen. Immediately contact a physician if respiration system irritation occurs, as well as vertigo, nausea or faint.
Following skin contact:	Remove contaminated clothing. Thoroughly wash with water and soap for 15 minutes.
Following eye contact:	Rinse the eyes using mild jet of clean water for at least 15 minutes with the eyelids held wide open. Contact a physician if irritation occurs.
Following ingestion:	DO NOT induce vomiting. Contact a physician if any of the symptoms occurs.
Self-protection of the first aider	-
<b>4.2. Most important symptoms and effects, both acute and delayed</b>	
Following inhalation:	Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system.
Following skin contact:	Prolonged and/or repeated exposure to low viscosity content may cause irritation and dermatitis, skin drying or cracking.

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	Following eye contact:	Eye irritation may occur during exposure to vapor concentrations above recommended level.
	Following ingestion:	If swallowing occurs, aspiration of the vomit may also occur and cause chemical pneumonitis or pulmonary oedema.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

<b>SECTION 5. Firefighting measures</b>		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Water spray, dry powder, CO <sub>2</sub>
	Unsuitable extinguishing media:	Water jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous byproducts of fire:	Carbon, nitrogen, sulphur and sodium oxides.
5.3.	Advice for firefighters	
	Evacuate the area. Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing).	
5.4.	Additional information	
	-	

<b>SECTION 6. Accidental release measures</b>		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	When disposing of small quantities use protective clothing. When disposing of large quantities use self-contained open-circuit compressed air breathing apparatus or self-contained closed-circuit air breathing apparatus.
	Accident prevention methods:	Secure a safety zone, remove all ignition sources, and in case of an accident inform the Emergency service (112) and the manufacturer or sender. Position a prohibition sign with symbols of flame and devices that cause sparks.
	Emergency procedures:	Remove or neutralize all factors that may exacerbate the condition, use all allowed means of containing the situation and use recommended means of personal protection.
6.1.2.	For emergency responders:	
	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	
	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and materials for containment and cleaning up	

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6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112).
6.4.	Reference to other sections	
	Refer to Section 5 for firefighting measures. Refer to Section 4 for first aid measures. Refer to Section 8 for personal protection requirements.	

**SECTION 7. Handling and storage**

7.1.	Precautions for safe handling	
7.1.1.	Protective measures	
	Measures to prevent fire:	No information available.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating. Avoid skin contact.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in a cool and well-ventilated place. Keep away from heat and direct solar radiation.
	Packaging materials:	Teflon, polypropylene, stainless steel, carbon steel.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	No information available.
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

**SECTION 8. Exposure controls/personal protection**

8.1.	Control parameters
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Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m <sup>3</sup>	
-	-	-	-	No information available

\* Source - material safety data sheet provided by the raw materials supplier

Substance:	-			
EC No:	-	CAS No:	-	

**DNEL**

**Industrial**

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity: -

**Consumer**

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

**PNEC**

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

**8.2. Exposure controls**

**8.2.1. Appropriate engineering controls**

Substance/mixture related measures to prevent exposure during identified uses:	Do not eat, drink or smoke in the workspace. Use personal protective equipment. Wash hands after handling the product and before eating and/or drinking.
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	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	See Section 7.2
8.2.2.	<b>Personal protection equipment:</b>	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	<b>Skin protection</b>	
	Hand protection:	In case prolonged or repeated contact with the product, use nitril rubber protective gloves.
	Other skin protection:	During everyday work use cotton clothing and suitable footwear, such as rubber boots or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values (or because of inadequate ventilation), use full gas mask equipped with brown filter A.
8.2.2.4.	Thermal hazards:	
8.2.3.	<b>Environmental exposure controls</b>	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

<b>SECTION 9. Physical and chemical properties</b>			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	Liquid	No information available
	Colour:	Green	No information available
	Odour:	No odor	No information available
	Odour threshold;	No information available	No information available

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	pH:	No information available	No information available
	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2.	Other information		
	-		

<b>SECTION 10.: Stability and reactivity</b>		
10.1.	Reactivity:	No information available
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	No information available
10.4.	Conditions to avoid:	Open flames and ignition sources.
10.5.	Incompatible materials:	Strong oxidants.
10.6.	Hazardous decomposition products:	Product decomposition will not occur at ambient temperature.

<b>SECTION 11. Toxicological information</b>	
11.1.	Information on toxicological effects
	Acute toxicity:

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Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results
Oral:	No information available	-	No information available	-	-
Dermal:	No information available	-	No information available	-	-
Inhalation:	No information available	-	No information available	-	-

**Specific target organ toxicity - single exposure (STOT-SE):**

	Specific effects	Target organ	Note
Oral:	No information available	No information available	-
Dermal:	No information available	No information available	-
Inhalation:	No information available	No information available	-

**Aspiration hazard:** Insignificant danger at normal handling temperature.

**Irritation and corrosion**

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	No information available	rabbit	Not irritating.	OECD	-
Serious eye damage/irritation	No information available	rabbit	Not irritating.	not specified	-

**Sensitization**

Skin sensitization:	No information available
Respiratory sensitization:	No information available

**Symptoms related to the physical, chemical and toxicological characteristics**

Oral exposure:	If swallowing occurs, aspiration of the vomit may also occur and cause chemical pneumonitis or pulmonary oedema.
Dermal exposure:	Prolonged and/or repeated exposure to low viscosity content may cause irritation and dermatitis, skin drying or cracking.
Inhalation exposure:	Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system.
Eye exposure:	Eye irritation may occur during exposure to vapor concentrations above recommended level.

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Repeated dose toxicity (subacute, subchronic, chronic)						
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	-				
Subacute dermal	No information available	-				
Subacute inhalation	No information available	-				
Subchronic oral	No information available	-				
Subchronic dermal	No information available	-				
Subchronic inhalation	No information available	-				
Chronic oral	No information available	-				
Chronic dermal	No information available	-				
Chronic inhalation	No information available	-				

Specific target organ toxicity - repeated exposure (STOT-RE):			
	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

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CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	No carcinogenicity studies were made, but since the product is not mutagenic and causes a minimal level of toxicity, it can be assumed that chronic exposure will not cause tumors.
Mutagenicity <i>in-vitro</i> :	No information available
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	No information available
Germ cell mutagenicity :	No information available
Reproductive toxicity:	No information available
Summary of evaluation of the CMR properties; :	
No information available	
<b>11.2. Practical experiences:</b>	
Classification observations:	No information available
Other observations:	No information available
<b>11.3. General notes:</b>	
-	

<b>SECTION 12. Ecological information</b>						
<b>12.1. Toxicity</b>						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub> = 2890 mg/l	96 hours	Pimephales promelas	OECD	-	-
Crustacea:	EC <sub>50</sub> < 100 mg/l	48 hours	Daphnia magna	No information available	-	-
Algae/aquatic plants:	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	No information available
Other organisms:	-	-	-	-	-	-
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	No information available

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Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	No information available
Algae/aquatic plants:	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	No information available
Other organisms:	-	-	-	-	-	-

**12.2. Persistence and degradability**

Abiotic degradation					
	Degradation half-lives		Method	Evaluation	Note
Marine water	No information available	information available	No information available	No information available	-
Fresh water	No information available	information available	No information available	No information available	-
Air	No information available	information available	No information available	No information available	-
Soil	No information available	information available	No information available	No information available	-

Biodegradation					
	% Degradation	Time (days)	Method	Evaluation	Note
	No information available				

**12.3. Bioaccumulative potential**

Octanol-water partition coefficient (log Kow)							
	Value	Concentration	pH	°C	Method	Evaluation	Note
	No information available	No information available	-	-	No information available	No information available	No information available

Bioconcentration Factor (BCF)					
	Value	Species	Method	Evaluation	Note

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15884 - 100000	Pimephales promelas (fish)	No information available	No information available	Exposure period: 2 to 304 days

**Chronic ecotoxicity**

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC <sub>50</sub>	No information available	No information available	No information available	No information available	Not expected.
Chronic toxicity on crustacea (Daphnia)	EC <sub>50</sub>	No information available	No information available	No information available	No information available	Not expected.

**12.4. Mobility in soil**

Known or predicted distribution in environmental compartments:						
The product is volatile, that causes degradation in air. No soil degradation is expected.						
Surface tension:						
Value	°C	Concentration	Method	Note		
No information available	No information available	No information available	No information available	-		

**Adsorption / desorption**

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-Water	No information available	No information available	No information available	No information available	-
Water-Air	No information available	No information available	No information available	No information available	-
Soil-Air	No information available	No information available	No information available	No information available	-

**12.5. Results of PBT and vPvB assessment**

No information available						

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12.6.	Other adverse effects
	No information available

**SECTION 13. Disposal considerations**

13.1.	Waste treatment methods
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13.1.1.	Product/Packaging disposal:
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	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
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13.1.2.	Waste codes/waste designations according to Low:
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	No information available
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13.1.3.	Waste treatment – relevant information:
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	Incinerating the product at high temperatures is recommended in order to avoid incomplete combustion products.
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13.1.4.	Sewage disposal – relevant information:
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	Waste must not be disposed of into the sewage system.
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13.1.5.	Other disposal recommendations:
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	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.
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13.1.6.	Relevant Community provisions:
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**SECTION 14. Transport information**

	Transporting/shipment by road (ADR)
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UN number:	Does not comply to transport regulations.
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UN proper shipping name:	-
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Transport hazard class(es):	-
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Packing group:	-
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Environmental hazards:	-
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Special precautions for user:	-
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	Transporting/shipment by rail (RID)
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UN number	Does not comply to transport regulations.
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UN proper shipping name:	-
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Transport hazard class(es):	-
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Packing group:	-
Environmental hazards:	-
Special precautions for user:	-

Transporting/shipment by inland waterways (ADN)	
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UN number:	Does not comply to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)	
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UN number:	Does not comply to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)	
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UN number:	Does not comply to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-

Further information:	Does not comply to transport regulations.
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<b>SECTION 15. Regulatory information</b>	
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15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorisation and/or restrictions on use	
	Authorisations:	-
	Restrictions:	-

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	Other EU regulations:	<p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act</p>
15.2.	Chemical safety assessment	
	None	

<b>SECTION 16. Other information</b>												
16.1.	Indication of changes:	-										
16.2.	Abbreviations and acronyms:	<table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td>LD<sub>50</sub></td> <td>Lethal dose, 50%</td> </tr> <tr> <td>LC<sub>50</sub></td> <td>Lethal concentration, 50%</td> </tr> <tr> <td>STOT-SE</td> <td>Specific target organ toxicity – single exposure</td> </tr> </table>	PBT	Stable, bioaccumulative and toxic	vPvB	Strongly stable and strongly bioaccumulative.	LD <sub>50</sub>	Lethal dose, 50%	LC <sub>50</sub>	Lethal concentration, 50%	STOT-SE	Specific target organ toxicity – single exposure
PBT	Stable, bioaccumulative and toxic											
vPvB	Strongly stable and strongly bioaccumulative.											
LD <sub>50</sub>	Lethal dose, 50%											
LC <sub>50</sub>	Lethal concentration, 50%											
STOT-SE	Specific target organ toxicity – single exposure											
16.3.	Key literature references and source of data:	-										
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)											
	Classification	Classification procedure										
	-	-										
16.5.	Relevant H statements (number and full text)											
	H: 315	Causes skin irritation.										
	319	Causes serious eye irritation.										
	335	May cause respiratory irritation.										
16.6.	Training advice:	-										

**SAFETY DATA SHEET**  
**According to Regulation (EC) No. 1907/2006**

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Trade name:	<b>FAST GREEN F.C.F. CONTRAST REAGENT</b>				
Product code:	FGKR-OT-X**	Date of compilation:	15 March 2017	Version:	2

16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.
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<b>ANNEX: Exposure scenario resulting to Chemical safety assessment</b>
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