

Trading name:	BIOWAX PLUS 56/58				
Product code:	BWPLUS-X**	Date of compilation:	18 June 2019.	Version:	4

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier	
Trading name:	BIOWAX PLUS 56/58
Chemical name:	-
Catalogue number:	BWPLUS-X**
1.2. Relevant identified uses of the substance or mixture and uses advised against	
Uses:	An optimal blend of paraffin wax and plastic polymers with melting point at 56/58°.
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
1.3. Details of the supplier of the safety data sheet	
Supplier:	BioGnost Ltd.
Address:	Medjugorska 59, Zagreb
Telephone number:	+385 1 2409997
Fax no.:	+385 1 2404039
e-mail of competent person:	msds@biognost.hr
National contact:	-
1.4. Emergency telephone number	
National Protection and Rescue Directorate:	112
Medical information:	+385 1 2348 342
Other information:	-

SECTION 2 HAZARDS INFORMATION

2.1. Classification of the substance or mixture	
2.1.1. Classification (REGULATION (EC) No. 1272/2008 (CLP))	
Hazard class and category code:	Hazard statements*:
Not identified as hazardous substance.	-
2.1.2. Additional information	
-	
*For full text of Hazard- and EU Hazard-statements: see Section 16	
2.2. Classification according to EC Directive Nr. 1272/2008 CLP)	
Product identification:	BIOWAX PLUS 56/58
Identification number:	-
Authorization no.:	-
Hazard pictograms:	-

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Signal word:	-
Hazard statements:	-
Precautionary statements:	-
Further information:	-
2.3. Other hazards	
	-

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS				
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
8002-74-2/ 232-315-6/ -	-	> 90	paraffin	-
9003-29-6/ 500-004-7/ -	-	< 6	poly(isobutene)	-
24937-78-8/ -/ -	-		ethylene vinyl acetate copolymer	-
Firm blend of paraffin hydrocarbons and microcrystalline waxes.				

SECTION 4 FIRST AID MEASURES	
4.1.	Description of first aid measures
	General notes: -
	Following inhalation: Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.
	Following skin contact: Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact: Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.
	Following ingestion: Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.
	Self-protection of the first aider: Treat symptomatically.
4.2.	Most important symptoms and effects, both acute and delayed

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	Following inhalation:	Under normal working conditions, no harmful effects are expected. Inhalation of gases during paraffin heating may irritate eyes, nose and throat.
	Following skin contact:	May cause irritation. Sensitive persons may experience redness and skin drying.
	Following eye contact:	May cause mild irritation that does not last. Sensitive persons may experience eye redness and lacrimation.
	Following ingestion:	High dose may cause nausea, vomiting, diarrhea, abdominal pain, bowel obstruction, and in rare cases may cause liver and brain damage.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5 FIREFIGHTING MEASURES		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Water spray, dry powder, CO ₂ or alcohol-resistant foam
	Unsuitable extinguishing media:	No information available
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Carbon monoxide, carbon dioxide. Hazardous gases may be liberated in the case of fire.
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
5.4.	Additional information	
	Do not contaminate the environment with extinguishing media.	

SECTION 6 ACCIDENTAL RELEASE MEASURES		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	

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6.3. Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures: Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up: It may be collected in a jar using paper towels or other absorbing material. If the wax is hot, let it cool down before cleaning. For removing cool wax, use non-sparking tools and scrape the wax in appropriate disposal jars. Use appropriate protective clothing.
6.3.3.	Other information: Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.4. Reference to other sections	
See Section 7 for information on safe handling. See Section 8 for information on personal protective equipment. See Section 13 for disposal information.	

SECTION 7 HANDLING AN STORAGE	
7.1. Precautions for safe handling	
7.1.1. Protection measures	
Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke. Use in well ventilated storage rooms.
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.	
7.2. Conditions for safe storage, including any incompatibilities	
Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
Packaging materials:	Manufacturer's original packaging.
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:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).

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7.3.	Specific end use(s)		
	Recommendations:	-	
	Industrial sector specific solutions:	-	

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Paraffin wax, smoke	8002-74-2	-/-	2/6	No information available

Substance name: -

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

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Air	No information available	
8.2. Exposure controls		
8.2.1. Engineering measures		
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	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:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2. Personal protection equipment		
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
	Other skin protection:	Choose the type of personal protection according to the type of work and possible effects. Use equipment such as apron, protective boots, and protective clothing for use against liquid chemicals
8.2.2.3.	Respiratory protection:	Not necessary. Necessary if there may be a risk of inhaling the heated material's vapor. Use an appropriate particle filter P1, white in color.
8.2.2.4.	Thermal hazards:	No information available
8.2.3. Environmental exposure controls		
	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

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

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9.1. Information on basic physical and chemical properties			
		Value	Method
	Physical state:	solid (pellets)	No information available
	Color:	transparent white	No information available
	Odor:	no odor	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point:	56 – 58 °C	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
	Vapor pressure:	No information available	No information available
	Vapor 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):	Not soluble	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			
	-		

SECTION 10 STABILITY AND REACTIVITY		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	No information available.
10.5.	Incompatible materials:	No information available.
10.6.	Hazardous decomposition products:	No information available.

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SECTION 11 TOXICOLOGICAL INFORMATION					
11.1. Information on toxicological effects					
Acute toxicity:					
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	-	LD ₅₀	-	-
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-
Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects	Target organ	Note		
Oral exposure:	No information available	No information available	-		
Dermal exposure:	No information available	No information available	-		
Inhalation exposure:	No information available	No information available	-		
Respiratory irritation: No information available					
Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	-	-	-	-
Eye irritation:	-	-	-	-	-
Sensitization					
Dermal exposure:	No information available				
Inhalation exposure:	No information available				
Symptoms related to the physical, chemical and toxicological characteristics					
Oral exposure:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.				
Dermal exposure:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.				
Inhalation exposure:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.				

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Eye exposure:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
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Repeated dose toxicity (subacute, subchronic, chronic)						
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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

Specific target organ toxicity – repeated exposure (STOT RE):			
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	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	-

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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	-

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	No information available
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:	-

11.2.	Practical experiences:
Remarks relevant for classification:	No information available
Other remarks:	No information available

11.3.	General notes:
	-

SECTION 12 ECOLOGICAL INFORMATION:

12.1.	Toxicity					
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

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Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	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	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

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

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

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Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:						
No information available						
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	information available	No information available	No information available	No information available	-
Water-air	No information available	information available	No information available	No information available	No information available	-
Soil-air	No information available	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						
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SECTION 13 DISPOSAL CONSIDERATIONS	
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	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. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-

SECTION 14 TRANSPORT INFORMATION	
	Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-

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Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

Inland waterway transport (ADN)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

Further information: The product is not subject to classification.

SECTION 15 REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations	
Authorization and/or restrictions of use	
Authorizations:	-
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 from 29 June 2000 on substances that damage the ozone layer;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about 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

SECTION 16 Other information																
16.1.	Indication of changes: -															
16.2.	<table border="0"> <tr> <td>Abbreviations and acronyms:</td> <td>PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td></td> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td></td> <td>LD₅₀</td> <td>Lethal dose, 50%</td> </tr> <tr> <td></td> <td>LC₅₀</td> <td>Lethal concentration, 50%</td> </tr> <tr> <td></td> <td>STOT-SE</td> <td>Specific target organ toxicity - single exposure</td> </tr> </table>	Abbreviations and acronyms:	PBT	Stable, bioaccumulative and toxic		vPvB	Strongly stable and strongly bioaccumulative.		LD ₅₀	Lethal dose, 50%		LC ₅₀	Lethal concentration, 50%		STOT-SE	Specific target organ toxicity - single exposure
Abbreviations and acronyms:	PBT	Stable, bioaccumulative and toxic														
	vPvB	Strongly stable and strongly bioaccumulative.														
	LD ₅₀	Lethal dose, 50%														
	LC ₅₀	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)															
	<table border="0"> <tr> <td>Classification</td> <td>Classification procedure</td> </tr> <tr> <td>-</td> <td>-</td> </tr> </table>	Classification	Classification procedure	-	-											
Classification	Classification procedure															
-	-															
16.5.	Relevant H statements (number and full text)															
	H: -															
16.6.	Training advice: -															

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16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>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.</p>
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<p>ANNEX: EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT</p>	
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