

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name : [WASH BUF 20x]

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Bioactiva diagnostica GmbH
Louisenstraße 137
61348 Bad Homburg – Germany
T:+49 6172 17102 0 F:+49 617217102 29

Email competent person

sds@kft.de

1.4. Emergency telephone number

Emergency number : +49 6172 17102 0 (available only during business hours from Monday – Friday 08:00 a.m. – 5:00 p.m.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 2 H315

Serious eye damage/eye irritation, Category 2 H319

Full text of H-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes skin irritation. Causes eye irritation.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

Precautionary statements (CLP) :

P280 - Wear protective gloves, eye protection, face protection.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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according to Regulation (EC) No. 1907/2006 (REACH)

Component	
ethanol (64-17-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
5-Bromo-5-nitro-1,3-dioxane (30007-47-7)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments

: Aqueous solution of special active agents

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ethanol substance with national workplace exposure limit(s) (GB)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5	≥ 1 – < 2.5	Flam. Liq. 2, H225 Eye Irrit. 2, H319
5-Bromo-5-nitro-1,3-dioxane	(CAS-No.) 30007-47-7 (EC-No.) 250-001-7	≥ 0.1 – < 0.25	Acute Tox. 4 (Oral), H302 (ATE=455 mg/kg bodyweight) Skin Corr. 1, H314 Eye Dam. 1, H318 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
ethanol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5	(50 ≤ C < 100) Eye Irrit. 2, H319
5-Bromo-5-nitro-1,3-dioxane	(CAS-No.) 30007-47-7 (EC-No.) 250-001-7	(0.1 ≤ C < 3) Eye Irrit. 2, H319 (0.1 ≤ C < 5) Skin Irrit. 2, H315

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Take off contaminated clothing. Wash skin with plenty of water. Cover wounds with sterile bandage. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for several minutes. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth out with water. Drink plenty of water. Do NOT induce vomiting. Call a poison center or a doctor if you feel unwell.

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according to Regulation (EC) No. 1907/2006 (REACH)

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact : Irritation.
Symptoms/effects after eye contact : Eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Not combustible. Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media : Strong water jet.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : release of harmful/irritant gases/vapours. Nitrogen oxides.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Concerning personal protective equipment to use, see section 8.
Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material, e.g.: sand, saw dust. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Wash away remainder with plenty of water.
Other information : Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment.
Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

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according to Regulation (EC) No. 1907/2006 (REACH)

Information about storage in one common storage facility

: Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

In vitro diagnostics.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

ethanol (64-17-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/m ³
WEL TWA (OEL TWA) [2]	1000 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

5-Bromo-5-nitro-1,3-dioxane (30007-47-7)	
DNEL/DMEL (Workers)	
Acute - systemic effects, dermal	7.78 µg/kg bodyweight/day
Acute - systemic effects, inhalation	27.4 µg/m ³
Long-term - systemic effects, dermal	7.78 µg/kg bodyweight/day
Long-term - systemic effects, inhalation	27.4 µg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	0.265 µg/L
PNEC aqua (marine water)	26.5 ng/l
PNEC aqua (intermittent, freshwater)	2.65 µg/L
PNEC aqua (intermittent, marine water)	0.265 µg/L
PNEC (Sediment)	
PNEC sediment (freshwater)	1.46 µg/kg dw
PNEC sediment (marine water)	0.146 µg/kg dw
PNEC (Soil)	
PNEC soil	0.136 µg/kg
PNEC (STP)	
PNEC sewage treatment plant	0.15 mg/l

ethanol (64-17-5)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	343 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	950 mg/m ³

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DNEL/DMEL (General population)	
Long-term - systemic effects, oral	87 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	114 mg/m ³
Long-term - systemic effects, dermal	206 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.96 mg/l
PNEC aqua (marine water)	0.79 mg/l
PNEC aqua (intermittent, freshwater)	2.75 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	3.6 mg/kg dwt
PNEC sediment (marine water)	2.9 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.63 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	0.38 kg/kg food
PNEC (STP)	
PNEC sewage treatment plant	580 mg/l

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep workplace clean and tidy as much as possible. Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:
Wear closed safety glasses. EN 166

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing. EN ISO 13688. EN 13034

Hand protection:					
Chemically resistant protective gloves. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,35	3 (> 0.65)	EN ISO 374

8.2.2.3. Respiratory protection

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according to Regulation (EC) No. 1907/2006 (REACH)

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Breathing apparatus with filter. ABEK-P2. EN 143. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: colourless.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not applicable
Lower explosive limit (LEL)	: Not available
Upper explosive limit (UEL)	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7 – 7.4 (20 °C)
Viscosity, kinematic	: Not available
Solubility	: Water: Miscible
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: Not determined
Vapour pressure	: Not available
Vapour pressure at 50 °C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20 °C	: Not available
Particle size	: Not applicable
Particle size distribution	: Not applicable
Particle shape	: Not applicable
Particle aspect ratio	: Not applicable
Particle aggregation state	: Not applicable
Particle agglomeration state	: Not applicable
Particle specific surface area	: Not applicable
Particle dustiness	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

VOC content : < 1 %

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according to Regulation (EC) No. 1907/2006 (REACH)

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available.

10.2. Chemical stability

No decomposition if stored normally.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

heat.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

5-Bromo-5-nitro-1,3-dioxane (30007-47-7)

LD50 oral rat	455 mg/kg bodyweight
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Skin corrosion/irritation	: Causes skin irritation. pH: 7 – 7.4 (20 °C)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 7 – 7.4 (20 °C)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)

5-Bromo-5-nitro-1,3-dioxane (30007-47-7)

STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.
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Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
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11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Before neutralisation, the product may represent a danger to aquatic organisms.
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according to Regulation (EC) No. 1907/2006 (REACH)

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

5-Bromo-5-nitro-1,3-dioxane (30007-47-7)	
LC50 - Fish [1]	0.68 mg/l (96h; Cyprinus carpio; (OECD 203 method))
EC50 - Crustacea [1]	1.32 mg/l (48 h; Daphnia magna; (OECD 202 method))
EC50 72h algae	0.265 mg/l (72 h; Pseudokirchneriella subcapitata; (OECD 201 method))
ErC50 algae	0.265 mg/l (72 h; Pseudokirchneriella subcapitata; (OECD 201 method))

12.2. Persistence and degradability

[WASH BUF 20x]	
Persistence and degradability	No additional information available.

5-Bromo-5-nitro-1,3-dioxane (30007-47-7)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	0 % (7 d; (OECD-Methode 301D))

ethanol (64-17-5)	
Persistence and degradability	Readily biodegradable.
Biodegradation	84 % (20 d)

12.3. Bioaccumulative potential

[WASH BUF 20x]	
Partition coefficient n-octanol/water (Log Pow)	Not determined
Bioaccumulative potential	No additional information available.

ethanol (64-17-5)	
Partition coefficient n-octanol/water (Log Kow)	-0.35 (20 °C)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

[WASH BUF 20x]	
Ecology - soil	No additional information available.

5-Bromo-5-nitro-1,3-dioxane (30007-47-7)	
Surface tension	71 mN/m (20 °C; 1000 mg/L; (OECD 115 method))

ethanol (64-17-5)	
Surface tension	22.31 mN/m (20 °C)

12.5. Results of PBT and vPvB assessment

[WASH BUF 20x]	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

[WASH BUF 20x]

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according to Regulation (EC) No. 1907/2006 (REACH)

Component	
ethanol (64-17-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
5-Bromo-5-nitro-1,3-dioxane (30007-47-7)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Other adverse effects : No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.
Product/Packaging disposal recommendations	: Dirty containers cannot be handled as normal waste. Disposal must be done according to official regulations.
European List of Waste (LoW) code	: 16 05 06* - laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals 15 01 02 - plastic packaging
HP Code	: HP4 - "Irritant — skin irritation and eye damage:" waste which on application can cause skin irritation or damage to the eye.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

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according to Regulation (EC) No. 1907/2006 (REACH)

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

Reference code	Applicable on
3(a)	ethanol
3(b)	[WASH BUF 20x] ; ethanol
40.	ethanol

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

VOC content : < 1 %

15.1.2. National regulations

United Kingdom

National regulations

: This safety data sheet is for informational purposes only and does not comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

Section	Changed item	Change	Comments
	General revision		

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer

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Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources : MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data : KFT Chemieservice GmbH
specification sheet: Im Leuschnerpark 3
D-64347 Griesheim

Phone: +49 6155-8981-400
Fax: +49 6155 8981-500
SDS Service: +49 6155 8981-522

Contact person : Christian Rank

Other information : This safety data sheet is for informational purposes only and does not comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Skin Corr. 1	Skin corrosion/irritation, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.

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Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.