

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

1.1 Product identifier

Trade name: Boule Con-Diff L/N/H 4.5ml

1.2 Uses

Relevant identified uses of the product: For in vitro diagnostic use as a control to monitor the performance of multi-parameter hematology instruments.

Uses advised against: The product should only be used according the relevant IFU (Instructions for Use) or the instrument manual.

1.3 Details of the supplier of the statement

Supplier: BOULE MEDICAL AB
Address: Domnarvsgatan 4, SE-163 53 Spånga, Sweden
Telephone No: +46(0)8 - 7447700
Telefax No: +46(0)8 - 7447720
E-mail: info@boule.se

1.4 Emergency telephone number (for information only)

Emergencies (24 hours): 112 (the European emergency number)
Health advice and information (24 hours): +44 (0) 845 4647 (UK only)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the mixture

2.1.1 CLASSIFICATION ACCORDING TO CLP [REGULATION (EC) NO 1272/2008]

Classification: See section 16.4 Information on the classification.

2.1.2 CLASSIFICATION ACCORDING TO DPD (COUNCIL DIRECTIVE 99/45/EC)

Classification: The product was not classified as a dangerous substance under the former legislation for classification and labeling of dangerous chemical substances and mixtures.

2.2 Label elements

Trade name: Boule Con-Diff L/N/H
Substances in the mixture: Names of the ingredients are not compulsory according to article 17 CLP.
Hazard Pictograms: Hazard Pictograms are not compulsory according to article 17 CLP.
Hazard Statements: Hazard Statements are not compulsory according to article 17 CLP.
Precautionary Statements: Precautionary Statements are not compulsory according to article 17 CLP.
Other labelling: EUH 208 Contains Kathon. May produce an allergic reaction.
The product contains blood cells and should be considered potentially infectious even though it is tested negative for Hepatitis B, Hepatitis C and HIV viruses. The product is marked with the symbol of the potentially infectious material.



2.3 Other hazards

PBT substance: YES NO NOT APPLICABLE
 vPvB substance: YES NO NOT APPLICABLE
 Physical hazards: No other known hazards.
 Health hazards: The product contains blood cells and should be considered potentially infectious even though it is tested negative for Hepatitis B, Hepatitis C and HIV viruses.
 Environmental hazards: No other known hazards.

2.4 Authorization (substance)

See section 15.1.2 Authorizations and restrictions according to Reach sections VII and VIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS □

3.1 Composition/information on ingredients

Substance name	Index No	CAS No	EC No	Registration No	
Kathon [reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no. 247-500-7) and 2-methyl-2H -isothiazol-3-one (EC no. 220-239-6) (3:1)]	613-167-00-5	55965-84-9	-	-	
	Classification according to DSD			Conc (w/w)	Other
	T; R23/24/25 C; R34 Xi; R43 N; R50/53			< 0.0015	-
	Classification according to CLP				
Acute Tox. 3; H301 H311 H331 Skin Corr. 1B; H314 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410					
For a complete explanation of the symbol letters and risk phrases go to section 16 Other information.					

SECTION 4: FIRST AID MEASURES □

4.1 Description of first aid measures

General description of the product: Bring this safety data sheet, safety instructions leaflet or label with you to the doctor treating you. First-aiders do normally not need protective equipment.

Inhalation: If the product is inhaled, and symptoms like shortness of breath or other symptoms of illness occur, fresh air and rest is recommended. If simple first aid does not produce a quick recovery, call the emergency number.

Skin contact: Wash with soap and water. In contact with chemical substances exposed clothes and shoes should normally be removed. The product does normally not possess any hazard to the exposed person or to first-aiders.

Eye contact: To prevent eye irritation, rinse immediately with a tempered, soft or low pressure water jet or eye wash for at least 5 minutes. If symptoms persist (intense stinging, pain, light sensitivity, poor vision) continue rinsing and seek medical assistance.

Ingestion: Drink a couple of glasses of water. If more than a small quantity has been ingested seek medical advice.

Notes for the doctor: Exposure does generally not possess any hazard to the health.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms:

Eye contact:	Tears, red eyes, pain, blurred vision, impaired but reversible vision.
Ingestion:	Irritation, nausea, vomiting
Skin contact:	Not expected.
Inhalation:	Cough, pain in nose and throat.

Delayed effects: Not expected.

4.3 Indication of immediate medical attention and special treatment needed

Specific/immediate treatment at the workplace: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES



5.1 Extinguishing media

Suitable extinguishing media: The product is not flammable. Extinguishing media should be chosen according to fire and surroundings.

Unsuitable extinguishing media: Water jets are not a suitable extinguishing media when extinguishing fire from chemical products.

5.2 Special hazards arising from the substance or mixture

Specific hazards: The product contains blood cells and should be considered potentially infectious even though it is tested negative for Hepatitis B, Hepatitis C and HIV viruses.

5.3 Advice for fire-fighters

General safety measures: Apply general fire safety precautions. Avoid inhalation of smoke fumes.

Safety measures during firefighting: Adequate protective equipment should be worn for all fire fighting. Protective equipment providing total coverage and an oxygen mask is recommended.



SECTION 6: ACCIDENTAL RELEASE MEASURES



6.1 Personal precautions, protective equipment and emergency procedures

General safety measures: After accidental release of flammable or volatile substances or substances that generates dust, ventilate the exposed area thoroughly. Use methods to minimize generation of dust and vapors.

Personal protective equipment: Avoid inhalation of vapors and exposure to eyes and skin. Always wear gloves when handling chemical substances.

Protection for emergency responders: See section 8.2.2 Personal protection.

6.2 Environmental precautions

General safety measures: None.

6.3 Methods and material for containment and cleaning up

Containment techniques: Specific containment is normally not necessary.
Methods for cleaning up: Collect spills. Absorb spill with vermiculite, dry sand, or adsorbent pads.

6.4 Reference to other sections

Sections 8 and 13: Information regarding personal protective equipment, see section 8.2
Exposure controls, and regarding waste disposal, see section 13 Disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

General requirements: The product contains blood cells and should be considered potentially infectious even though it is tested negative for Hepatitis B, Hepatitis C and HIV viruses. A risk assessment of the handling must always be made by the employer based on the specific conditions prevailing at the workplace. The above information may constitute one of several inputs to develop appropriate instructions for safe use, prevention and handling of waste, storage, disposal, etc. of product.
Standard industry hygiene applies. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

Measures to prevent fire: The product is not flammable or combustible.

Measures to prevent aerosol, vapors and dust generation: Not applicable.

Measures to protect the environment: See section 6.2 Environmental precautions.

7.2 Conditions for safe storage, including any incompatibilities

General conditions for safe storage: Stored in a closed container in the refrigerator (2-10 ° C). Avoid temperature below 0 ° C.

Specific storage requirements: Stored in a closed container in the refrigerator (2-10 ° C). Avoid temperature below 0 ° C.

Packaging compatibilities: 3.0ml glass tubes.

Specific designs for storage rooms or vessels: Stored in a closed container in the refrigerator (2-10 ° C). Avoid temperature below 0 ° C.

7.3 Specific end use(s)

Exposure scenario: YES, see attached ES. NO

Industry or sector specific guidance: YES, see below in this section. NO

Reference to guidance: Source: - Issuing date: -

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 NATIONAL OCCUPATIONAL EXPOSURE LIMITS OR COMMUNITY OCCUPATIONAL EXPOSURE LIMITS

National limit values: YES, see table below. NO

Community limit values: YES, see table below. NO

Substance name	CAS No	Occupational exposure limits			
		Long-term (8 h)		Short-term (15 min)	
		ppm	mg/m ³	ppm	mg/m ³
Not applicable	--	-	-	--	--

8.1.2 DN(M)EL / PNEC

8.1.2.1 DN(M)EL

Substance: Kathon

Exposure - health	DN(M)EL	Exposure group	
		Workers	Others ¹
Acute exposure, skin contact systemic effects	DNEL	No information	No information
Acute exposure, inhalation, systemic effects	DNEL	No information	No information
Acute exposure, ingestion, systemic effects	DNEL	Not applicable	No information
Acute exposure, skin contact, local effects	DNEL	No information	No information
Acute exposure, inhalation, local effects	DNEL	No information	No information
Chronic (repeated) exposure, skin contact, systemic effects	DNEL	No information	No information
Chronic (repeated) exposure, inhalation, systemic effects	DNEL	No information	No information
Chronic (repeated) exposure, ingestion, systemic effects	DNEL	Not applicable	No information
Chronic (repeated) exposure, skin contact, local effects	DNEL	No information	No information
Chronic (repeated) exposure, inhalation, local effects	DNEL	No information	No information

Mixture is not classified as hazardous, no specific information collected

8.1.2.2 PNEC

Substance: Kathon

Exposure – compartment	PNEC
Water (freshwater)	No information
Water (marine water)	No information
Water (intermittent releases)	No information
STP (Sewage Treatment Plant)	No information
Sediment (freshwater/marine)	Not relevant
Soil	No information

Mixture is not classified as hazardous, no specific information collected

8.1.3 MONITORING

Controls of air pollution: If more than one substance occur or can be expected to occur in the working environment, the risk for interacting effects with increasing toxicity shall be assessed. In the assessment of exposure conditions, consideration shall be paid, not only to the concentration of air contaminants in the respiratory air, but also to the workload and to the possibility of certain substances being absorbed percutaneously. The person planning and conducting measurement of air contaminants shall have sufficient knowledge for the purpose. Measurements should be taken using a method and equipment suitable for the purpose. Exposure measurements shall refer to conditions during normal operations. If necessary they should also indicate exposure under other conditions. Exposure measurements shall be conducted in the breathing zone and on a sufficient number of persons for the exposure to be judged with reference to all persons exposed.

8.1.4 RISK MANAGEMENT MEASURES

General recommendations: If a risk assessment has shown that there is a risk for exposure at a workplace, the work shall be arranged, conducted and followed up in such a way that the exposure will be as low as is practically possible. In order to reduce the risk, substitution shall by preference be undertaken. Where it is not reasonably practicable to prevent exposure to a substance hazardous to health, the employer shall take risk reduction measures, in order of priority: (a) The design and use of appropriate work processes, systems and engineering controls and the provision and use of suitable work equipment and materials; (b) The control of exposure at source, including adequate ventilation systems and appropriate organizational measures; (c) Where adequate control of exposure cannot be achieved by other means, the provision of suitable personal protective equipment in addition to the measures required by sub-paragraphs (a) and (b).

Control banding: Using a control banding approach in order to identify appropriate risk management measures, is only applicable for the relevant identified uses, see section 1 Identification of the substance/mixture and of the company. No specific risk assessment limitations can be given, since different models of control banding are available.

8.2 Exposure controls

8.2.1 APPROPRIATE ENGINEERING CONTROLS

Precautionary measures: No respiratory protection is ordinarily required under normal conditions of use and when adequate ventilation is ensured. In accordance with good industrial hygiene practices, precautions should be taken to avoid breathing of material, e.g. dust, see section 8.1.3 Risk management measures.

8.2.2 PERSONAL PROTECTION

Requirements for protection equipment: Personal protective clothing should meet recommended standards. This is checked with the clothing supplier. Ensure that all protective clothing requirements are observed. Regular checks should be performed to ensure that protective clothing is both effective and complete.

Eye/face protection: With risk of exposure to the eyes, always wear protective glasses [EN 166 (Personal eye-protection - Specifications)].

Skin protection: Always wear gloves when handling chemical substances [EN 374 (Protective gloves against chemicals and micro-organisms)]. For advice about suitable gloves for the type of work, period and frequency of exposure, contact the glove supplier.

Suitable glove material
(example only), see 8.2.2.
Skin protection:

Material	Thickness	Breakthrough time
Nitrile, neoprene, pva	-	-

Body protection:

Standard protective clothing.

Respiratory protection

With risk of exposure to the respiratory system, use a gas filter (removal of organic substances) and a dust filter P3 [EN 143 (particle filters)], [EN 140 (Half masks and quarter masks), EN 149 (Filtering half masks to protect against particles)].

Thermal hazards:

None.

8.2.3 ENVIRONMENTAL EXPOSURE CONTROLS

General risk management measures: No specific measures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES □

9.1 Information on basic physical and chemical properties

Property	Value	Method / Remarks
Physical state:	Liquid	-
Granulometry:	Not applicable	-
Color as supplied:	Dark red	-
Odor:	None	-
Odor threshold:	Not applicable	-
pH:	No information	-
Melting point / freezing point:	0 °C	-
Initial boiling point and boiling range:	100 °C	-
Flash point:	Not applicable	-
Evaporation rate:	Not applicable	-
Flammability (solid, gas):	Non flammable	-
Upper/lower flammability or explosive limits:	Non explosive	-
Vapor pressure:	No information	-
Vapor density:	Not applicable	-
Density:	Ca 1 g/cm ³	-
Solubility in water:	Completely soluble	-
Solubility in organic solvents:	Insoluble in organic solvents	-
Partition coefficient: n-octanol/water:	Not applicable	-
Auto-ignition temperature:	Not applicable	-
Decomposition temperature:	Not applicable	-
Viscosity:	Not applicable	-
Explosive properties:	Non explosive	-
Oxidizing properties:	No oxidizing properties	-

9.2 Other safety information

Property	Value	Method / Remarks
Solubility in fat:	Insoluble in fat	-
Conductivity:	No information	-
Dissociation constant in water (pKa):	Not applicable	-

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Reactivity hazards: The mixture has a low reactivity.

10.2 Chemical stability

Stability under normal handling and storage: Stable mixture under normal and intended handling conditions and storage, e.g. temperature, pressure etc.

Stabilizers: -

10.3 Possibility of hazardous reactions

Hazardous reactions: Not expected to cause any hazardous reactions.

Hazardous conditions: See section 10.4 Conditions to avoid.

10.4 Conditions to avoid

Hazardous conditions: None.

Risk management measures: See section 7 Handling and storage.

10.5 Incompatible materials

Specific materials: Strong acids and bases.

Risk management measures: See section 7 Handling and storage.

10.6 Hazardous decomposition products

Known/anticipated hazardous decomposition products: See section 10.3 Possibility of hazardous reactions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.1 MIXTURE - INFORMATION ON RELEVANT HAZARD CLASSES

Acute toxicity:

Ingestion: Based on available data, the classification criteria are not met. See section 2.3 Other hazards.

Skin contact: Based on available data, the classification criteria are not met.

Inhalation: Based on available data, the classification criteria are not met.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitization: Based on available data, the classification criteria are not met. The mixture might produce an allergic reaction in already sensitized individuals.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.
Specific target organ toxicity – single exposure: Based on available data, the classification criteria are not met.
Specific target organ toxicity – repeated exposure: Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.

11.2 Brief summaries of the information derived from the application of Annexes VII to XI

Summary: Information is given to each hazard class in section 11.1.1 Substance - Information on relevant hazard classes.
CMR properties cat. 1A and 1B: The mixture contains no substances which meet the criteria to be classified for CMR properties according to CLP.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity - substance

12.1.1 TOXICITY AFTER SHORT AND LONG TERM EXPOSURE

Summary: The mixture is not expected to be dangerous for the aquatic or terrestrial environment from short-term or long-term exposure.

12.1.2 IMPACT ON SEWAGE TREATMENT PLANTS

Summary: The mixture is not expected to be dangerous for wastewater treatment plants.

12.2 Persistence and degradability

Biotic degradability: The mixture contains substances in very low concentrations that are not readily degradable.

Abiotic degradability: No information

12.3 Bio accumulative potential

Log P_{ow} and/or BCF value: The mixture contains substances in very low concentrations that are bio accumulating.

12.4 Mobility in soil

Environmental distribution: All substances in the mixture are expected to be distributed to the water phase and mobile in soil.

12.5 Results of PBT and vPvB assessment

PBT substance: YES NO NOT APPLICABLE
vPvB substance: YES NO NOT APPLICABLE

12.6 Other adverse effects

General: No known adverse effects.

12.7 Brief summaries of the information derived from the application of Annexes VII to XI

Summary: See information in sections 12.1 – 12.4.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Disposal considerations

13.1.1 CLASSIFICATION OF WASTE

Hazardous waste: YES NO

Waste designations according to EWC: 18 01 03 Hazardous waste, infectious

Packaging: 15 01 07 Glass packaging.

13.1.2 HANDLING OF WASTE

General information: Before handling waste, see section 8 Exposure controls/Personal protection. During application the product may have been contaminated with hazardous substances, which properties in the waste may not be the same as the original product's properties. It is therefore always the user's responsibility to classify the waste. Hazardous waste must be transported by an approved transporter. For regular transport of hazardous waste, the user is responsible for providing a transport document.

Handling of waste product: Handled as hazardous waste.

Handling of packaging: Also the primary packaging (glass tube) should be handled as infectious waste.

SECTION 14: TRANSPORT INFORMATION

14.1 General information

Dangerous goods: YES NO

SECTION 15: REGULATORY INFORMATION

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

15.1.1 REGULATIONS/LEGISLATION REGARDING SAFETY, HEALTH AND ENVIRONMENT

General information: The employer shall inform the employees concerned of the health hazards and accident risks entailed by hazardous chemical substances occurring at the worksite and how these risks are avoided. Information shall also be supplied concerning occupational exposure limit values for the substances occurring and concerning other Provisions applying to the work, as well as concerning the routines existing for internal chemicals control. The employer shall ascertain that the employees concerned have understood the information.

Work environment: The Control of Substances Hazardous to Health Regulations 2002 No. 2677. (UK only)
EH40/2005 Workplace exposure limits. (UK only)

Environment: The Producer Responsibility Obligations (Packaging Waste) Regulations 1997 No. 648. (UK only)

Safety: -

15.1.2 AUTHORIZATIONS AND RESTRICTIONS ACCORDING TO REACH SECTIONS VII AND VIII

Authorization (substance): YES NO

Authorization No: -

Restriction (substance/mixture): YES NO

15.1.3 SPECIAL RULES ON PACKAGING ACCORDING TO CLP [(EC) No 1272/2008]

Consumer product: YES NO
Child-resistant fastening: YES NO
Tactile warning of danger: YES NO

15.2 Chemical Safety Assessment (CSR)

Chemical Safety Assessment: YES, mixture YES, substance(s) NO

SECTION 16: OTHER INFORMATION



16.1 Indication of changes

Information to the user: When the information under particular sections in the safety data sheet is changed in accordance with Reach art 31 (9), it is shown by ticking the respective checkbox to the right of that section. The specific changes are given on request.

Changes in current edition: New SDS.

16.2 Abbreviations and acronyms

@: Used instead of the word "at".
BCF: **B**io **c**oncentration **F**actor. The equilibrium concentration of a chemical in a living organism, expressed as the ratio C_b/C_w (C_b = concentration in biota, C_w = concentration in water).
BW: **B**ody **w**eight.
CAS No: **C**hemical **A**bstracts **S**ervice number.
Cat: Category. Subdivision of a hazard class, used in classification.
CLP: **C**lassification, **L**abelling and **P**ackaging of chemical substances and mixtures. Short for: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
CMR properties: **C**arcinogenic, **M**utagenic or toxic for **R**eproduction
Control banding: Control banding (CB) is a technique used to guide the assessment and management of workplace risks. It is a generic technique that determines a control measure (for example dilution ventilation, engineering controls, containment, etc.) based on a range or "band" of hazards (such as skin/eye irritant, very toxic, carcinogenic, etc.) and exposures (small, medium, large exposure). It is an approach that is based on two pillars; the fact that there are a limited number of control approaches, and that many problems have been met and solved before.
CSR: **C**hemical **S**afety **R**eport.
DMEL: **D**erived **M**inimal **E**ffect **L**evel.
DNEL: **D**erived **N**o-**E**ffect **L**evel.
DSD: **D**angerous **S**ubstances **D**irective. Council Directive 67/548/EEC.
EC₅₀: **E**ffect **C**oncentration. Statistically derived median concentration of a substance in an environmental medium expected to produce a certain effect in 50 % of test organisms in a given population under a defined set of conditions.
EC No: The EC number, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union.
Einecs: **E**uropean **I**nventory of **E**xisting **C**ommercial **C**hemical **S**ubstances.

Elincs:	The E uropean L ist of N otified C hemical S ubstances.
EN 140:	Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking.
EN 143:	Respiratory protective devices - Particle filters - Requirements, testing, marking.
EN 149:	Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking.
EN 166:	Personal eye-protection – Specifications.
EN 374:	Protective gloves against chemicals and micro-organisms - Part 3: Determination of resistance to permeation by chemicals.
EN 388:	Protective gloves against mechanical risks.
ES:	E xposure s cenario.
EWC:	The European Waste Catalogue . The EWC is a hierarchical list of waste descriptions established by Commission Decision 2000/532/EC.
Index No:	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
LOAEL:	L owest O bservable A dverse E ffect L evel. The lowest dose tested which gives a specific adverse effect.
LC ₅₀ :	L ethal C oncentration. In ecotoxicology, the LC ₅₀ is the concentration which kills 50 % of a population of one species, within a specified period of time.
LD ₅₀ :	L ethal D ose. The LD ₅₀ is the dose of a substance which kills 50 % of a population of one species and is expressed as weight (mg, g) or as weight per weight of test animal (mg/kg).
Log Pow:	The potential for bioaccumulation - determined by using the octanol/water partition coefficient - is reported as log "Pow" by the EU, whereas the GHS criteria refer to log "Kow".
NOAEC:	N o O bserved A dverse E ffect C oncentration. The highest concentration tested in an experiment that does not show adverse effects. Expressed as daily dose weight per weight of animal (mg/m ³).
NOAEL:	N o O bserved A dverse E ffect L evel. The highest dose tested in an experiment that does not show adverse effects. Expressed as daily dose weight per weight of animal (mg/kg).
NOEC:	N o O bserved E ffect C oncentration. The highest concentration tested in an experiment that does not show any effect on the organism. Expressed as concentration (mg/l) or (mg/m ³).
NOEL:	N o O bserved E ffect L evel. The highest dose tested in an experiment that does not show any effect on the animal. Expressed as daily dose per weight of animal (mg/kg).
NLP:	N o- L onger P olymers L ist.
OECD:	O rganization for E conomic C o-operation and D evelopment. The OECD Guidelines for the Testing of Chemicals are a collection of internationally agreed test methods. They cover tests for the physical-chemical properties, human health effects and environmental effects.
PBT substance:	P ersistent, b io accumulative and t oxic substance.
pH:	pH is a measure of the acidity or basicity of an aqueous solution .
pKa:	The symbol for the acid dissociation constant at logarithmic scale.
PNEC:	P redicted N o- E ffect C oncentration.
ppm:	p arts p er m illion.

Reach: **Registration, Evaluation, Authorization and Restriction of Chemicals.**
REACH is the **European** Community Regulation on **chemicals** and their safe use.

vPvB substance: **Very persistent and very bio accumulative substance.**

WEL: **Workplace Exposure Limits.**

16.3 Key literature references and sources for data

References: REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

16.4 Information on the classification

16.4.1 CLASSIFICATION ACCORDING TO CLP [REGULATION (EC) NO 1272/2008]

Classification: The product is not classified as a dangerous substance under the current legislation for classification and labelling of dangerous chemical substances and mixtures.

16.4.2 EVALUATION METHOD USED FOR CLASSIFICATIONS ACCORDING TO ARTICLE 9 CLP







Evaluation method: 9.1 (chapt 1 sect II CLP) 9.2 (other methods than art 8.3)
 9.3 (expert judgement) 9.4 (bridging principles)
 9.5 other methods described in part 3 and 4 annex I

16.5 Relevant H-phrases

16.5.1 R PHRASES ACCORDING TO CLP (IN SECTION 3)

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Harmful if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

16.5.2 DANGER CODES ACCORDING TO CLP (IN SECTION 3)

Hazard class / Hazard statement	Hazard pictogram	Signal word
Acute toxicity H301 H311 H331	GHS06 	Danger
Skin corrosion / irritation H314	GHS05 	Danger
Skin corrosion / irritation H315	GHS07 	Warning
Serious eye damage/eye irritation H318	GHS05 	Danger
Respiratory or skin sensitization H317	GHS07 	Warning
Hazardous to the aquatic environment H400 H410	GHS09 	Warning

16.6 Training advice

General training:

The employer shall inform the employees concerned of the health hazards and accident risks entailed by hazardous chemical substances occurring at the worksite and how these risks are avoided. Information shall also be supplied concerning occupational exposure limit values for the substances occurring and concerning other Provisions applying to the work, as well as concerning the routines existing for internal chemicals control. The employer shall ascertain that the employees concerned have understood the information.

Specific training:

No special training aside from handling human blood samples necessary for this product.

16.7 Exposure scenarios (ES)

ES for the mixture:

ES are not given as an attachment to this safety data sheet. Relevant information for the mixture is given under each specific section.