

Safety Data Sheet
according to 2020/878

SECTION 1: Identification of the substance/mixture and of the company/undertaking	
1.1 Product identifier <ul style="list-style-type: none"> • Trade name: • Article number: 	AmpliTest <i>Helicobacter pylori</i> (Real Time PCR) BAC45-100
1.2 Relevant identified uses of the substance or mixture and uses advised against	<u>Recommended use:</u> Reagent kit for detecting DNA sequences specific for <i>Helicobacter pylori</i> using Real-Time PCR technique. <u>Non-recommended use:</u> Not specified.
1.3 Details of the supplier of the safety data sheet	Amplicon Sp. z o.o. ul. Klecińska 125 54-413 Wrocław Poland + 48 739 223 268 e-mail: contact@amplicon.pl
1.4 Emergency telephone number:	On weekdays, from 8:30 am to 3:30 pm: +48 739 223 268, or at any time: local emergency telephone number

SECTION 2: Hazard identification	
2.1 Classification of the substance or mixture (according to Regulation (EC) No 1272/2008) <ul style="list-style-type: none"> • Strong toxicity to aquatic organisms • Chronic toxicity to aquatic organisms 	No data available No data available
2.2 Label elements <ul style="list-style-type: none"> • Hazard pictograms • Signal word • Hazard statements 	Void Void Void
2.3. Other hazards	Some risks associated with individual components of this product are not significant because these substances are present at concentrations below GHS threshold values, undergo a change in physical state, or the mixture is buffered to pH 4-9. The product does not contain compounds considered persistent, bioaccumulative, or toxic, or very persistent and very bioaccumulative in quantities of 0.1% or higher.

SECTION 3: Composition/information on ingredients	
3.1/3.2 Chemical characterisation	Component WATER: Grade I water Components IC, NC, PC: A mixture of substances containing water, tris-HCl, EDTA, and nucleic acids in quantities that are not hazardous to health at the levels present in the mixture. Component RM: A mixture of water, enzymes, glycerol (≤ 5%), nucleic acids, and additional substances that are not hazardous to health at the levels present in the mixture.
3.3 Remarks	None

SECTION 4: First aid measures	
4.1 Description of first aid measures <ul style="list-style-type: none"> • General information • After inhalation • After skin contact 	If necessary, consult a physician. Show them this safety data sheet. Move the patient to fresh air, keep warm, and provide resuscitation if necessary. If symptoms worsen, seek medical attention.

<ul style="list-style-type: none"> • After eye contact • After swallowing 	<p>Remove contaminated clothing. Rinse skin or mucous membranes with warm water. Use soap if possible. Flush eyes with plenty of water or rinse eyes with open eyes for at least 15 minutes. Do not induce vomiting. Rinse the mouth and drink plenty of water. Never put anything into the mouth of an unconscious person.</p>
4.2. The most important acute and delayed symptoms and effects of exposure	It may cause mild eye irritation. The product does not pose a significant risk under normal conditions of use.
4.3. Instructions regarding any immediate medical attention and special treatment of the victim	No additional instructions.

SECTION 5: Firefighting measures	
5.1. Extinguishing media	Water spray, fire extinguishers containing foam, dry powder or carbon dioxide.
5.2 Special hazards arising from the substance or mixture	The mixture is non-flammable. During decomposition at high temperatures, carbon oxides, nitrogen oxides, hydrogen chloride, phosphorus oxides, potassium oxides, magnesium oxides, lithium oxides, sulfur, and hydrogen sulfide are formed.
5.3 Advice for firefighters	The packaging burns like paper or plastic. In the event of the formation of a large amount of toxic substances, use a self-contained breathing apparatus and protective clothing to prevent contact with toxic substances.

SECTION 6: Accidental release measures	
6.1 Personal precautions, protective equipment and emergency procedures	
<p>Non-rescue Personnel: Evacuate unnecessary personnel. Avoid inhaling vapors and contact with eyes, skin, and clothing.</p> <p>Rescue Personnel: Avoid releasing materials into the environment or prevent further release of substances into the environment. Wear protective clothing.</p>	
6.2 Environmental precautions:	
<p>Avoid disposing of the product into the natural environment. Do not pour the product into sewage systems. Prevent further release of the product into the environment if such a situation arises.</p>	
6.3 Methods and material for containment and cleaning up:	
<p>Absorb the product with a paper towel or any absorbent material. Clean the contaminated surface with plenty of water.</p>	

SECTION 7: Handling and storage of substances and mixtures	
7.1 Precautions for safe handling	
<p>The mixture should only be used by qualified personnel according to its intended purpose and operating instructions. Ensure good ventilation in the room. Avoid inhaling vapors and contact with eyes, skin, and clothing. Adhere to safety and hygiene rules. Wash hands and other exposed skin areas after exposure to the mixture. Remove clothing that has come into contact with the mixture.</p> <ul style="list-style-type: none"> • Information about protection against explosions and fires: No special measures required 	
7.2 Conditions for safe storage, including any incompatibilities	
<ul style="list-style-type: none"> • Storage: After delivery, the mixture should be stored at a temperature of -20°C in its original packaging. • Further information about storage conditions: Do not store together with alkalis, strong acids, oxidizing or reducing agents, alkali metals, acidic chlorides, or phosphorus halides. 	
7.3 Specific end use(s)	
No further relevant information available	

SECTION 8: Exposure controls**8.1 Control parameters****Components with limit values that require monitoring at the workplace:**Glycerol: 10 mg/m³ (time-weighted average)**8.2 Exposure controls**

- **Technical measures:** Good ventilation, surfaces resistant to chemical agents.
- **General:** Avoid unnecessary exposure. Follow safety and hygiene requirements.
- **Eye protection:** Use equipment compliant with EN166 standards.
- **Hand protection:** Protective gloves (synthetic gloves) meeting the requirements of EN374 standard and EU Directive 89/686/EEC.
- **Personal protective equipment:** Wear laboratory clothing with long sleeves.
- **Inhalation protection:** Not required.
- **Thermal hazards:** None under normal conditions of use.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

- **Form:** Liquid
- **Color:** Colorless
- **Odor:** Odorless
- **Odor threshold:** Undefined
- **pH:** Data not available
- **Melting point:** Not determined
- **Boiling point:** Not determined
- **Flash point:** Not applicable
- **Flammability:** Not applicable
- **Decomposition temperature:** Not determined
- **Self-ignition:** The product is not easily combustible
- **Explosion hazard:** The product does not pose an explosion hazard
- **Explosive limits:**
Lower: Not applicable
Upper: Not applicable
- **Vapor pressure at 20 °C:** Data not available
- **Density:** ~1 g/mL
- **Relative density:** Not determined
- **Vapor density:** Not determined
- **Evaporation rate:** Not determined
- **Solubility in water:** Not applicable
- **Partition coefficient (n-octanol/water):** Not determined
- **Viscosity:**
dynamic: Not determined
kinematic: Not determined
- **Solvent content:** ~100%

9.2 Other information: No further relevant information available**SECTION 10: Stability and reactivity**

10.1 Reactivity	The mixture is stable under normal conditions.
10.2. Chemical stability	The product is stable if used according to recommended storage conditions.
10.3 Possibility of hazardous reactions	No dangerous reactions known
10.4 Conditions to avoid	No further relevant information available
10.5 Incompatible materials	Bases, strong acids, oxidizing agents, reducing agents, alkali metals, acid chlorides, phosphorus halides.
10.6 Hazardous decomposition products:	During decomposition at high temperatures, carbon oxides, nitrogen oxides, hydrogen chloride, phosphorus oxides, potassium oxides, magnesium oxides, lithium oxides, sulfur oxides, and hydrogen sulfide are formed.

SECTION 11: Toxicological information				
11.1 Information on the hazard classes defined in Regulation (EC) 1272/2008				
Glycerol	LD50	orally	Rat	12600 mg/kg
		inhalation (4 hours)	Rat	2,75 mg/L
		dermally	Rabbit	10000 mg/kg
			Guinea pig	56750 g/kg
Finished product	Acute toxicity	Not classified. Not classified. Based on currently available data, the classification criteria are not met.		
	Skin irritation	Not classified. Not classified. Based on currently available data, the classification criteria are not met.		
	Serious eye damage/irritation	Not classified. Not classified. Based on currently available data, the classification criteria are not met.		
	Skin or respiratory sensitization	Not classified. Not classified. Based on currently available data, the classification criteria are not met.		
	Mutagenic effect on reproductive cells	Not classified. Not classified. Based on currently available data, the classification criteria are not met.		
	Carcinogenic effect	Not classified. Not classified. Based on currently available data, the classification criteria are not met.		
	Specific organ toxicity	Not classified. Not classified. Based on currently available data, the classification criteria are not met.		
	Risk of aspiration	Not classified. Not classified. Based on currently available data, the classification criteria are not met.		
	Potential adverse effects on human health and symptoms	The product does not pose a significant risk under the expected conditions of normal use.		

SECTION 12: Ecological information			
12.1 Toksyczność			
Glycerol	LC50	fish (<i>Salmo gairdneri</i>) 96 hours	Not classified
		Bacteria, activated sediment	> 1000 mg/L
	EC50	Daphnia (<i>Daphnia magna</i> , effect on movement) 24 hours.	> 10000 mg/L
	Ecology - water		Not classified
12.2 Persistence and degradability		No data	
12.3 Bioaccumulative potential		No data	
12.4 Mobility in soil		Ability to mix with water	
12.5 Results of PBT and vPvB assessment		The mixture does not meet the PBT and vPvB criteria	
12.6 Properties disrupting the functioning of the hormonal system		No data	
12.7 Other harmful effects		No data	

SECTION 13: Disposal considerations	
13.1 Methods of waste disposal	
<ul style="list-style-type: none"> • Mixture: Disposal should be entrusted to a licensed company specialized in processing laboratory waste. • Contaminated packaging: Disposal should be entrusted to a licensed company specialized in processing laboratory waste. 	

SEKCJA 14: Transport information	
14.1 UN number	ADR, ADN, IMDG, IATA: Not regulated
14.2 UN proper shipping name	ADR, ADN, IMDG, IATA: Not regulated
14.3 Transport hazard class(es)	ADR, ADN, IMDG, IATA: Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards:	The mixture does not pose a threat to the environment
14.6 Special precautions for user	Not regulated
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

- EU REACH Regulation (EC) No 1907/2006
- Regulation (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006

15.2 Chemical safety assessment

- A Chemical Safety Assessment has not been carried out

SECTION 16: Other information**16.1 Abbreviations used**

PBT: Persistent, Bioaccumulative, and Toxic
vPvB: very Persistent and very Bioaccumulative

16.2 Information for the reader

The provided information is deemed accurate but not necessarily complete and should only serve as a guideline. AMPLICON Sp. z o.o. is not liable for any damages related to the use or contact with the above product.

This safety data sheet has been compiled based on the safety data sheet provided by the manufacturer and/or online databases, as well as applicable regulations regarding hazardous substances and chemical preparations.

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