

Version: 00



Kit:

Product code	Product Name
GVS-B5705-24	Genvinset HLA-B57v5, 24 tests
GVS-B5705-48	Genvinset HLA-B57v5, 48 tests

Kit components:

Product code	Product Name
GVS-B57v5-PM	Genvinset HLA-B57v5 Primer Mix
GVS-B57v5-MM	Genvinset HLA-B57v5 Master Mix
GVS-B57v5-C+	Genvinset HLA-B57v5 Positive Control
GVS-RB	Genvinset Reaction Blank

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-PM-Genvinset HLA-B57v5 Primer Mix



Version: 00
Revision date: 16/12/2020

Page 1 of 7
Print date: 16/12/2020

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: Genvinset HLA-B57v5 Primer Mix
Product Code: GVS-B57v5-PM

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

Real-Time PCR primer mix for detection of HLA B*57:01 allele with TaqMan hydrolysis probes.

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **Blackhills Diagnostic Resources, S.L.U.**
Address: CL. Camino del Pílon 86, Casa 7 Local 50011
City: Zaragoza
Province: Zaragoza
Telephone: (+34) 976 094 603
E-mail: info@bdrdiagnostics.com
Web: <http://www.bdrdiagnostics.com/>

1.4 Emergency telephone number: 112 (EU). Outside Europe, call your local emergency service.

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the mixture.

The product is not classified as hazardous within the meaning of Regulation (EU) No 1272/2008.

2.2 Label elements.

2.3 Other hazards.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not Applicable.

3.2 Mixtures.

This mixture does not contain substances that pose a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, are not assigned a Community exposure limit in the workplace, and are not classified as PBT/vPvB or included in the Candidate List.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-PM-Genvinset HLA-B57v5 Primer Mix



Version: 00
Revision date: 16/12/2020

Page 2 of 7
Print date: 16/12/2020

Skin contact.

Remove contaminated clothing.

Ingestion.

Keep calm. NEVER induce vomiting.

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

No known acute or delayed effects from exposure to the product.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the mixture.

Special risks.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

Pick up the spill with non-combustible absorbent materials (soil, sand, vermiculite, diatomite, etc.). Pour the product and the absorbent in an appropriate container. The contaminated area should be immediately cleaned with an appropriate decontaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-PM-Genvinset HLA-B57v5 Primer Mix



Version: 00
Revision date: 16/12/2020

Page 3 of 7
Print date: 16/12/2020

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store the product between -18°C and -30°C, in a dry and well-ventilated place.

As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store according to local legislation. Observe indications on the label.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %		
Uses:	Real-Time PCR primer mix for detection of HLA B*57:01 allele with TaqMan hydrolysis probes.		
Breathing protection:			
If the recommended technical measures are observed, no individual protection equipment is necessary.			
Hand protection:			
PPE:	Protective gloves.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.		
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
If the product is handled correctly, no individual protection equipment is necessary.			
Skin protection:			
PPE:	Protective clothing.		
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.		
CEN standards:	EN 340		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.		
PPE:	Work footwear.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN ISO 13287, EN 20347		
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.		



-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-PM-Genvinset HLA-B57v5 Primer Mix



Version: 00
Revision date: 16/12/2020

Page 4 of 7
Print date: 16/12/2020

Observations: Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Appearance: Light
Colour: Colourless
Odour: Odourless
Odour threshold: N.A./N.A.
pH: N.A./N.A.
Melting point: N.A./N.A.
Boiling Point: N.A./N.A.
Flash point: N.A./N.A.
Evaporation rate: N.A./N.A.
Inflammability (solid, gas): N.A./N.A.
Lower Explosive Limit: N.A./N.A.
Upper Explosive Limit: N.A./N.A.
Vapour pressure: N.A./N.A.
Vapour density: N.A./N.A.
Relative density: N.A./N.A.
Solubility: N.A./N.A.
Liposolubility: N.A./N.A.
Hydrosolubility: Completely miscible
Partition coefficient (n-octanol/water): N.A./N.A.
Auto-ignition temperature: N.A./N.A.
Decomposition temperature: N.A./N.A.
Viscosity: N.A./N.A.
Explosive properties: N.A./N.A.
Oxidizing properties: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

9.2 Other information.

Dropping point: N.A./N.A.
Blink: N.A./N.A.
Kinematic viscosity: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions until expire date noted on vial (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-PM-Genvinset HLA-B57v5 Primer Mix



Version: 00
Revision date: 16/12/2020

Page 5 of 7
Print date: 16/12/2020

11.1 Information on toxicological effects.

There are no tested data available on the product.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

Splatters in the eyes can cause irritation and reversible damage.

a) acute toxicity;
Not conclusive data for classification.

b) skin corrosion/irritation;
Not conclusive data for classification.

c) serious eye damage/irritation;
Not conclusive data for classification.

d) respiratory or skin sensitisation;
Not conclusive data for classification.

e) germ cell mutagenicity;
Not conclusive data for classification.

f) carcinogenicity;
Not conclusive data for classification.

g) reproductive toxicity;
Not conclusive data for classification.

h) STOT-single exposure;
Not conclusive data for classification.

i) STOT-repeated exposure;
Not conclusive data for classification.

j) aspiration hazard;
Not conclusive data for classification.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity of the substances present.

12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.

No information is available on the degradability of the substances present. No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Other adverse effects.

No information is available about other adverse effects for the environment.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-PM-Genvinset HLA-B57v5 Primer Mix



Version: 00
Revision date: 16/12/2020

Page 6 of 7
Print date: 16/12/2020

SECTION 13 DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code.

Transportation is not dangerous.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

Product classification according to Annex I of Directive 2012/18/EU (SEVESO III): N/A

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

It is recommended that the product only be employed for the purposes advised.

Abbreviations and acronyms used:

CEN: European Committee for Standardization.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-PM-Genvinset HLA-B57v5 Primer Mix



Version: 00
Revision date: 16/12/2020

Page 7 of 7
Print date: 16/12/2020

PPE: Personal protection equipment.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2015/830.

Regulation (EC) No 1907/2006.

Regulation (EU) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation 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.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-MM-Genvinset HLA-B57v5 Master Mix



Version: 00
Revision date: 16/12/2020

Page 1 of 8
Print date: 16/12/2020

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: Genvinset HLA-B57v5 Master Mix
Product Code: GVS-B57v5-MM

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

Real-Time PCR reaction mix for detection of HLA B*57:01 allele with TaqMan hydrolysis probes.

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **Blackhills Diagnostic Resources, S.L.U.**
Address: CL. Camino del Pílon 86, Casa 7 Local 50011
City: Zaragoza
Province: Zaragoza
Telephone: (+34) 976 094 603
E-mail: info@bdrdiagnostics.com
Web: http://www.bdrdiagnostics.com/

1.4 Emergency telephone number: 112 (EU). Outside Europe, call your local emergency service.

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the mixture.

The product is not classified as hazardous within the meaning of Regulation (EU) No 1272/2008.

2.2 Label elements.

2.3 Other hazards.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not Applicable.

3.2 Mixtures.

Substances posing a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, assigned a Community exposure limit in the workplace, and classified as PBT/vPvB or included in the Candidate List:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	specific concentration limit
: 57-50-1 : 200-334-9	[1] sucrose	10 - 25 %	-	-

(*)The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

[1] Substance with a Community workplace exposure limit (see section 8.1).

SECTION 4: FIRST AID MEASURES.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-MM-Genvinset HLA-B57v5 Master Mix



Version: 00
Revision date: 16/12/2020

Page 2 of 8
Print date: 16/12/2020

4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

Remove contaminated clothing.

Ingestion.

Keep calm. NEVER induce vomiting.

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

No known acute or delayed effects from exposure to the product.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the mixture.

Special risks.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

Pick up the spill with non-combustible absorbent materials (soil, sand, vermiculite, diatomite, etc.). Pour the product and the absorbent in an appropriate container. The contaminated area should be immediately cleaned with an appropriate decontaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-MM-Genvinset HLA-B57v5 Master Mix



Version: 00
Revision date: 16/12/2020

Page 3 of 8
Print date: 16/12/2020

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store the product between -18°C and -30°C, in a dry and well-ventilated place.

As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store according to local legislation. Observe indications on the label.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

Work exposure limit for:

Name	CAS No.	Country	Limit value	ppm	mg/m ³
sucrose	57-50-1	United Kingdom [1]	Eight hours		10
			Short term		20
		Éire [2]	Eight hours		10
			Short term		20
		United States [3] (Cal/OSHA)	Eight hours		10 (Total dust) 5 (Respirable fraction)
			Short term		
		United States [4] (NIOSH)	Eight hours		10 (Total dust) 5 (Respirable fraction)
			Short term		
		United States [5] (OSHA)	Eight hours		15 (Total dust) 5 (Respirable fraction)
			Short term		

[1] According Limit Value (IOELV) list in 2nd Indicative Occupational Exposure adopted by Health and Safety Executive.

[2] According Code of Practice for the Safety, Health and Welfare at Work (Chemicals Agents) Regulations adopted by Health and Safety Authority (HSA).

[3] California Division of Occupational Safety and Health (Cal/OSHA) Permissible Exposure Limits (PELs).

[4] National Institute for Occupational Safety and Health. NIOSH Recommendations for occupational safety and health, Compendium of Policy Documents and Statements, January, 1992, DHHS (NIOSH) Publication No. 92-100.

[5] Occupational Safety and Health Administration, United States Department of Labor. Permissible Exposure limits (PELs), California Division of Occupational Safety and Health (Cal/OSHA) Permissible Exposure Limits (PELs).

The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-MM-Genvinset HLA-B57v5 Master Mix



Version: 00
Revision date: 16/12/2020

Page 4 of 8
Print date: 16/12/2020

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %
Uses:	Real-Time PCR reaction mix for detection of HLA B*57:01 allele with TaqMan hydrolysis probes.
Breathing protection:	
If the recommended technical measures are observed, no individual protection equipment is necessary.	
Hand protection:	
PPE:	Protective gloves.
Characteristics:	«CE» marking, category II.
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.
Material:	PVC (polyvinyl chloride)
Breakthrough time (min.):	> 480
Material thickness (mm):	0,35
Eye protection:	
If the product is handled correctly, no individual protection equipment is necessary.	
Skin protection:	
PPE:	Protective clothing.
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.
CEN standards:	EN 340
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.
PPE:	Work footwear.
Characteristics:	«CE» marking, category II.
CEN standards:	EN ISO 13287, EN 20347
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Appearance: Light
Colour: Colourless
Odour: Odourless
Odour threshold: N.A./N.A.
pH: N.A./N.A.
Melting point: N.A./N.A.
Boiling Point: N.A./N.A.
Flash point: > 60 °C
Evaporation rate: N.A./N.A.
Inflammability (solid, gas): N.A./N.A.
Lower Explosive Limit: N.A./N.A.
Upper Explosive Limit: N.A./N.A.
Vapour pressure: N.A./N.A.
Vapour density: N.A./N.A.
Relative density: N.A./N.A.
Solubility: N.A./N.A.
Liposolubility: N.A./N.A.
Hydrosolubility: Completely miscible
Partition coefficient (n-octanol/water): N.A./N.A.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-MM-Genvinset HLA-B57v5 Master Mix



Version: 00
Revision date: 16/12/2020

Page 5 of 8
Print date: 16/12/2020

Auto-ignition temperature: N.A./N.A.
Decomposition temperature: N.A./N.A.
Viscosity: N.A./N.A.
Explosive properties: N.A./N.A.
Oxidizing properties: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

9.2 Other information.

Dropping point: N.A./N.A.
Blink: N.A./N.A.
Kinematic viscosity: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions until expire date noted on vial (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on toxicological effects.

There are no tested data available on the product.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

Splatters in the eyes can cause irritation and reversible damage.

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

Not conclusive data for classification.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Not conclusive data for classification.

h) STOT-single exposure;

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-MM-Genvinset HLA-B57v5 Master Mix



Version: 00
Revision date: 16/12/2020

Page 6 of 8
Print date: 16/12/2020

Not conclusive data for classification.

i) STOT-repeated exposure;
Not conclusive data for classification.

j) aspiration hazard;
Not conclusive data for classification.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity of the substances present.

12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.
No information is available on the degradability of the substances present. No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

Information about the bioaccumulation of the substances present.

Name	Bioaccumulation			
	Log Pow	BCF	NOECs	Level
sucrose CAS No: 57-50-1 EC No: 200-334-9	-2,7	-	-	Very low

12.4 Mobility in soil.

No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Other adverse effects.

No information is available about other adverse effects for the environment.

SECTION 13 DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-MM-Genvinset HLA-B57v5 Master Mix



Version: 00
Revision date: 16/12/2020

Page 7 of 8
Print date: 16/12/2020

14.1 UN number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code.

Transportation is not dangerous.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

Product classification according to Annex I of Directive 2012/18/EU (SEVESO III): N/A

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles:

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
46. (a) Nonylphenol C ₆ H ₄ (OH)C ₉ H ₁₉ CAS 25154-52-3 EC 246-672-0 (b) Nonylphenol ethoxylates (C ₂ H ₄ O) _n C ₁₅ H ₂₄ O	Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0,1 % by weight for the following purposes: (1) industrial and institutional cleaning except: - controlled closed dry cleaning systems where the washing liquid is recycled or incinerated, - cleaning systems with special treatment where the washing liquid is recycled or incinerated. (2) domestic cleaning; (3) textiles and leather processing except: - processing with no release into waste water, - systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin); (4) emulsifier in agricultural teat dips; (5) metal working except: uses in controlled closed systems where the washing liquid is recycled or incinerated; (6) manufacturing of pulp and paper; (7) cosmetic products; (8) other personal care products except: spermicides; (9) co-formulants in pesticides and biocides. However national authorisations for pesticides or biocidal products containing nonylphenol ethoxylates as co-

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-MM-Genvinset HLA-B57v5 Master

Mix

Version: 00

Revision date: 16/12/2020



Page 8 of 8

Print date: 16/12/2020

	formulant, granted before 17 July 2003, shall not be affected by this restriction until their date of expiry.
46a. Nonylphenol ethoxylates (NPE) (C ₂ H ₄ O) _n C ₁₅ H ₂₄ O	<ol style="list-style-type: none">1. Shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.2. Paragraph 1 shall not apply to the placing on the market of second-hand textile articles or of new textile articles produced, without the use of NPE, exclusively from recycled textiles.3. For the purposes of paragraphs 1 and 2, "textile article" means any unfinished, semi-finished or finished product which is composed of at least 80 % textile fibres by weight, or any other product that contains a part which is composed of at least 80 % textile fibres by weight, including products such as clothing, accessories, interior textiles, fibres, yarn, fabrics and knitted panels.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

It is recommended that the product only be employed for the purposes advised.

Abbreviations and acronyms used:

BCF: Bioconcentration factor.
CEN: European Committee for Standardization.
EC50: Half maximal effective concentration.
PPE: Personal protection equipment.
LC50: Lethal concentration, 50%.
LD50: Lethal dose, 50%.
Log Pow: Logarithm of the partition octanol-water.
NOEC: No observed effect concentration.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2015/830.

Regulation (EC) No 1907/2006.

Regulation (EU) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation 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.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-C+-Genvinset HLA-B57v5 Positive Control



Version: 00
Revision date: 16/12/2020

Page 1 of 7
Print date: 16/12/2020

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: Genvinset HLA-B57v5 Positive Control
Product Code: GVS-B57v5-C+

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

Evaluate test validity.

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **Blackhills Diagnostic Resources, S.L.U.**
Address: CL. Camino del Pílon 86, Casa 7 Local 50011
City: Zaragoza
Province: Zaragoza
Telephone: (+34) 976 094 603
E-mail: info@bdrdiagnostics.com
Web: <http://www.bdrdiagnostics.com/>

1.4 Emergency telephone number: 112 (EU). Outside Europe, call your local emergency service.

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the mixture.

The product is not classified as hazardous within the meaning of Regulation (EU) No 1272/2008.

2.2 Label elements.

2.3 Other hazards.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not Applicable.

3.2 Mixtures.

This mixture does not contain substances that pose a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, are not assigned a Community exposure limit in the workplace, and are not classified as PBT/vPvB or included in the Candidate List.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-C+-Genvinset HLA-B57v5 Positive Control



Version: 00
Revision date: 16/12/2020

Page 2 of 7
Print date: 16/12/2020

Skin contact.

Remove contaminated clothing.

Ingestion.

Keep calm. NEVER induce vomiting.

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

No known acute or delayed effects from exposure to the product.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the mixture.

Special risks.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

Pick up the spill with non-combustible absorbent materials (soil, sand, vermiculite, diatomite, etc.). Pour the product and the absorbent in an appropriate container. The contaminated area should be immediately cleaned with an appropriate decontaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-C+-Genvinset HLA-B57v5 Positive Control



Version: 00
Revision date: 16/12/2020

Page 3 of 7
Print date: 16/12/2020

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store the product between -18°C and -30°C, in a dry and well-ventilated place.

As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store according to local legislation. Observe indications on the label.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %		
Uses:	Evaluate test validity.		
Breathing protection:			
If the recommended technical measures are observed, no individual protection equipment is necessary.			
Hand protection:			
PPE:	Protective gloves.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.		
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
If the product is handled correctly, no individual protection equipment is necessary.			
Skin protection:			
PPE:	Protective clothing.		
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.		
CEN standards:	EN 340		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.		
PPE:	Work footwear.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN ISO 13287, EN 20347		
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.		



-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-C+-Genvinset HLA-B57v5 Positive Control



Version: 00
Revision date: 16/12/2020

Page 4 of 7
Print date: 16/12/2020

Observations: Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Appearance: Light
Colour: Colourless
Odour: Odourless
Odour threshold: N.A./N.A.
pH: N.A./N.A.
Melting point: N.A./N.A.
Boiling Point: N.A./N.A.
Flash point: N.A./N.A.
Evaporation rate: N.A./N.A.
Inflammability (solid, gas): N.A./N.A.
Lower Explosive Limit: N.A./N.A.
Upper Explosive Limit: N.A./N.A.
Vapour pressure: N.A./N.A.
Vapour density: N.A./N.A.
Relative density: N.A./N.A.
Solubility: N.A./N.A.
Liposolubility: N.A./N.A.
Hydrosolubility: Completely miscible
Partition coefficient (n-octanol/water): N.A./N.A.
Auto-ignition temperature: N.A./N.A.
Decomposition temperature: N.A./N.A.
Viscosity: N.A./N.A.
Explosive properties: N.A./N.A.
Oxidizing properties: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

9.2 Other information.

Dropping point: N.A./N.A.
Blink: N.A./N.A.
Kinematic viscosity: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions until expire date noted on vial (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-C+-Genvinset HLA-B57v5 Positive Control



Version: 00
Revision date: 16/12/2020

Page 5 of 7
Print date: 16/12/2020

11.1 Information on toxicological effects.

There are no tested data available on the product.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

Splatters in the eyes can cause irritation and reversible damage.

a) acute toxicity;
Not conclusive data for classification.

b) skin corrosion/irritation;
Not conclusive data for classification.

c) serious eye damage/irritation;
Not conclusive data for classification.

d) respiratory or skin sensitisation;
Not conclusive data for classification.

e) germ cell mutagenicity;
Not conclusive data for classification.

f) carcinogenicity;
Not conclusive data for classification.

g) reproductive toxicity;
Not conclusive data for classification.

h) STOT-single exposure;
Not conclusive data for classification.

i) STOT-repeated exposure;
Not conclusive data for classification.

j) aspiration hazard;
Not conclusive data for classification.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity of the substances present.

12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.

No information is available on the degradability of the substances present. No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Other adverse effects.

No information is available about other adverse effects for the environment.

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-C+-Genvinset HLA-B57v5 Positive Control



Version: 00
Revision date: 16/12/2020

Page 6 of 7
Print date: 16/12/2020

SECTION 13 DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code.

Transportation is not dangerous.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

Product classification according to Annex I of Directive 2012/18/EU (SEVESO III): N/A

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

It is recommended that the product only be employed for the purposes advised.

Abbreviations and acronyms used:

CEN: European Committee for Standardization.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-B57v5-C+-Genvinset HLA-B57v5 Positive Control



Version: 00

Revision date: 16/12/2020

Page 7 of 7

Print date: 16/12/2020

PPE: Personal protection equipment.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2015/830.

Regulation (EC) No 1907/2006.

Regulation (EU) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation 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.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-RB-Genvinset Reaction Blank



Version: 2
Revision date: 20/04/2020

Page 1 of 7
Print date: 20/04/2020

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: Genvinset Reaction Blank
Product Code: GVS-RB

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

Contamination control.

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **Blackhills Diagnostic Resources, S.L.U.**
Address: CL. Camino del Pílon 86, Casa 7 Local 50011
City: Zaragoza
Province: Zaragoza
Telephone: (+34) 976 094 603
E-mail: info@bdrdiagnostics.com
Web: <http://www.bdrdiagnostics.com/>

1.4 Emergency telephone number: 112 (EU). Outside Europe, call your local emergency service.

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the mixture.

The product is not classified as hazardous within the meaning of Regulation (EU) No 1272/2008.

2.2 Label elements.

2.3 Other hazards.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not Applicable.

3.2 Mixtures.

This mixture does not contain substances that pose a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, are not assigned a Community exposure limit in the workplace, and are not classified as PBT/vPvB or included in the Candidate List.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-RB-Genvinset Reaction Blank



Version: 2
Revision date: 20/04/2020

Page 2 of 7
Print date: 20/04/2020

Remove contaminated clothing.

Ingestion.

Keep calm. NEVER induce vomiting.

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

No known acute or delayed effects from exposure to the product.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the mixture.

Special risks.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

Pick up the spill with non-combustible absorbent materials (soil, sand, vermiculite, diatomite, etc.). Pour the product and the absorbent in an appropriate container. The contaminated area should be immediately cleaned with an appropriate decontaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-RB-Genvinset Reaction Blank



Version: 2
Revision date: 20/04/2020

Page 3 of 7
Print date: 20/04/2020

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store the product between -18°C and -30°C, in a dry and well-ventilated place.

As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store according to local legislation. Observe indications on the label.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Apart from the uses mentioned in section 1.2, no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %		
Uses:	Contamination control.		
Breathing protection:			
If the recommended technical measures are observed, no individual protection equipment is necessary.			
Hand protection:			
PPE:	Protective gloves.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.		
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
If the product is handled correctly, no individual protection equipment is necessary.			
Skin protection:			
PPE:	Protective clothing.		
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.		
CEN standards:	EN 340		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.		
PPE:	Work footwear.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN ISO 13287, EN 20347		
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.		
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident		



-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-RB-Genvinset Reaction Blank



Version: 2
Revision date: 20/04/2020

Page 4 of 7
Print date: 20/04/2020

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Appearance: Light
Colour: Colourless
Odour: Odourless
Odour threshold: N.A./N.A.
pH: N.A./N.A.
Melting point: N.A./N.A.
Boiling Point: N.A./N.A.
Flash point: N.A./N.A.
Evaporation rate: N.A./N.A.
Inflammability (solid, gas): N.A./N.A.
Lower Explosive Limit: N.A./N.A.
Upper Explosive Limit: N.A./N.A.
Vapour pressure: N.A./N.A.
Vapour density: N.A./N.A.
Relative density: N.A./N.A.
Solubility: N.A./N.A.
Liposolubility: N.A./N.A.
Hydrosolubility: Completely miscible
Partition coefficient (n-octanol/water): N.A./N.A.
Auto-ignition temperature: N.A./N.A.
Decomposition temperature: N.A./N.A.
Viscosity: N.A./N.A.
Explosive properties: N.A./N.A.
Oxidizing properties: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

9.2 Other information.

Dropping point: N.A./N.A.
Blink: N.A./N.A.
Kinematic viscosity: N.A./N.A.
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions until expire date noted on vial (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on toxicological effects.

There are no tested data available on the product.
Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.
Splatters in the eyes can cause irritation and reversible damage.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-RB-Genvinset Reaction Blank



Version: 2
Revision date: 20/04/2020

Page 5 of 7
Print date: 20/04/2020

- a) acute toxicity;
Not conclusive data for classification.
- b) skin corrosion/irritation;
Not conclusive data for classification.
- c) serious eye damage/irritation;
Not conclusive data for classification.
- d) respiratory or skin sensitisation;
Not conclusive data for classification.
- e) germ cell mutagenicity;
Not conclusive data for classification.
- f) carcinogenicity;
Not conclusive data for classification.
- g) reproductive toxicity;
Not conclusive data for classification.
- h) STOT-single exposure;
Not conclusive data for classification.
- i) STOT-repeated exposure;
Not conclusive data for classification.
- j) aspiration hazard;
Not conclusive data for classification.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity of the substances present.

12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.
No information is available on the degradability of the substances present. No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

12.4 Mobility in soil.

No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Other adverse effects.

No information is available about other adverse effects for the environment.

SECTION 13 DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-RB-Genvinset Reaction Blank



Version: 2
Revision date: 20/04/2020

Page 6 of 7
Print date: 20/04/2020

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR: Transportation is not dangerous.

IMDG: Transportation is not dangerous.

ICAO/IATA: Transportation is not dangerous.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

14.6 Special precautions for user.

Not applicable. Transportation is not dangerous.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code.

Transportation is not dangerous.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

Product classification according to Annex I of Directive 2012/18/EU (SEVESO III): N/A

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

It is recommended that the product only be employed for the purposes advised.

Abbreviations and acronyms used:

CEN: European Committee for Standardization.

PPE: Personal protection equipment.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2015/830.

Regulation (EC) No 1907/2006.

Regulation (EU) No 1272/2008.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)

GVS-RB-Genvinset Reaction Blank



Version: 2
Revision date: 20/04/2020

Page 7 of 7
Print date: 20/04/2020

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation 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.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.