

Version: 04



Kit:

Product code	Product Name
GVS-NP-24	Genvinset HLA Narcolepsy, 24 tests
GVS-NP-48	Genvinset HLA Narcolepsy, 48 tests

Kit components:

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

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

GVS-NP-PM-Genvinset HLA Narcolepsy Primer Mix



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Version 04 (replaces version 03)

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

1.1 Product identifier.

Product Name: Genvinset HLA Narcolepsy Primer Mix
Product Code: GVS-NP-PM

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

Real-Time PCR primer mix for detection of HLA DQB1*06:02 alleles 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
City: 50011 - Zaragoza
Province: Zaragoza
Telephone: (+34) 976 094 603
E-mail: info@bdrdiagnostics.com
Web: <http://www.bdrdiagnostics.com/>

1.4 Emergency telephone number: (+34) 976 094 603 (Only available during office hours; Monday-Friday; 08:30-17:30)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008:

Carc. 2 : Suspected of causing cancer.

Repr. 1B : May damage fertility or the unborn child.

2.2 Label elements.

Labelling in accordance with Regulation (EC) No 1272/2008:

Pictograms:



Signal Word:

Danger

Hazard statements:

H351 Suspected of causing cancer.

H360D May damage fertility or the unborn child.

Precautionary statements:

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear gloves and protective clothing

P501 Dispose of the contents or container to an authorised waste manager

EUH statements:

Restricted to professional users.

Contains: formamide

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2.3 Other hazards.

The mixture does not contain substances classified as PBT.
The mixture does not contain substances classified as vPvB.
The mixture does not contain any endocrine disrupting properties substances.

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	Specifics concentration limits and Acute toxicity estimate
Index No: 616-052-00-8 CAS No: 75-12-7 EC No: 200-842-0 Registration No: 01-2119496064-35-XXXX	[5] formamide	1 - 10 %	Carc. 2, H351 - Repr. 1B, H360D	-
Index No: 017-002-00-2 CAS No: 7647-01-0 EC No: 231-595-7 Registration No: 01-2119484862-27-XXXX	[1] hydrogen chloride	0 - 1 %	Acute Tox. 3 *, H331 - Skin Corr. 1A, H314	-

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

* See Regulation (EC) No. 1272/2008, Annex VI, section 1.2.

[1] Substance with a European Union exposure limit in the workplace (see section 8.1).

[5] Substance included in the list established under Article 59, paragraph 1, REACH (Candidate substance).

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Delayed effects may occur after the exposure to the product.

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. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

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

Long-term chronic exposure may result in injury to certain organs or tissues.

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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. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

SECTION 5: FIREFIGHTING MEASURES.

The product is NOT classified as flammable, in case of fire the following measures should be taken:

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 substance or mixture.

Special risks.

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. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

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.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

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.

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 according to local legislation. Observe indications on the label. Store the containers between -30 and -18 °C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising

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agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

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
hydrogen chloride	7647-01-0	European Union [1]	Eight hours	5	8
			Short term	10	15

[1] According both Binding Occupational Exposure Limits (BOELVs) and Indicative Occupational Exposure Limits (IOELVs) adopted by Scientific Committee for Occupational Exposure Limits to Chemical Agents (SCOEL).

The product does NOT contain substances with Biological Limit Values.

Concentration levels DNEL/DMEL:

Name	DNEL/DMEL	Type	Value
formamide CAS No: 75-12-7 EC No: 200-842-0	DNEL (Workers)	Inhalation, Chronic, Local effects	6,66 (mg/m ³)
	DNEL (Workers)	Inhalation, Chronic, Systemic effects	0,66 (mg/m ³)
hydrogen chloride CAS No: 7647-01-0 EC No: 231-595-7	DNEL (Workers)	Inhalation, Chronic, Local effects	8 (mg/m ³)

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.

DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

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 DQB1*06:02 alleles with TaqMan hydrolysis probes.		
Breathing protection:			
If the recommended technical measures are observed, no individual protection equipment is necessary.			
Hand protection:			
PPE:	Disposable laboratory gloves		
Characteristics:	Powder-free nitrile or latex gloves. They prevent contamination of hands with biological and chemical fluids, but they do not prevent punctures and needlestick injuries.		
CEN standards:	EN 374-1, En 374-2, En 374-4, En 374-5, EN 420-EN, 16523-1:2015		
Maintenance:	They should be stored in cool, dark places without being exposed to direct sunlight, fluorescent lights, X-rays, ozone and moisture.		
Observations:	The gloves should be the correct size, and fit the hand without being too loose or too tight. They should always be used with clean and dry hands.		
Material:	Latex	Breakthrough time (min.):	> 30
			Material thickness (mm):
Eye protection:			
If the product is handled correctly, no individual protection equipment is necessary.			
Skin protection:			
PPE:	Protective clothing.		

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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. 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.
Observations:	
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.

Physical state: Liquid

Colour: Colourless

Odour: Odourless

Odour threshold: Not available (not known).

Melting point: 0 °C (Pour point (ASTM D 9766))

Freezing point: 0 °C (Methods of freezing temperature (BS 4695))

Boiling point or initial boiling point and boiling range: 100 °C (Estimations in base on the Regulation (CE) N°1272 / 2008 indications.)

Flammability: Not available (Not relevant for this type of product).

Lower explosion limit: Not available due to the nature/properties of the product

Upper explosion limit: Not available due to the nature/properties of the product

Flash point: Not available due to the nature/properties of the product

Auto-ignition temperature: Not available (not known).

Decomposition temperature: Not available (not known).

pH: 7-8 (pH Meter/potentiometric/electrometric method)

Kinematic viscosity: Not available (not known).

Solubility: Not available (not known).

Hydrosolubility: Water-soluble (Fully mixable)

Liposolubility: Not available (not known).

Partition coefficient n-octanol/water (log value): Not applicable (Does not apply to mixtures).

Vapour pressure: Not available (not known).

Absolute density: 1100 kg/m³ (calculation/estimation)

Relative density: 1,1 (Pycnometer (ISO 758))

Relative vapour density: Not available (not known).

Particle characteristics: Not applicable (Applies to solids only).

9.2 Other information

Other safety characteristics

Formation of explosible dust/air mixtures:

The particle characteristics to which the data apply: Se aplica únicamente a los sólidos

Viscosity: Not available due to the nature/properties of the product

Dropping point: Not available due to the nature/properties of the product

Blink: Not available due to the nature/properties 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).

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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 hazard classes as defined in Regulation (EC) N° 1272/2008.

There are no tested data available on the product.

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

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

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;

Product classified:

Carcinogen, Category 2: Suspected of causing cancer.

g) reproductive toxicity;

Product classified:

Reproductive toxicant, Category 1B: May damage fertility or the unborn child.

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.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

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

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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
formamide CAS No: 75-12-7 EC No: 200-842-0	-1,51	-	-	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 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

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.

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.

14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: 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.

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14.5 Environmental hazards.

Transportation is not dangerous.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION.

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

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
30. Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively.	<p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none">- as substances,- as constituents of other substances, or,- in mixtures, <p>for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:</p> <ul style="list-style-type: none">- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,- the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008. <p>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p>'Restricted to professional users'.</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <ul style="list-style-type: none">(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;(b) cosmetic products as defined by Directive 76/768/EEC;(c) the following fuels and oil products:<ul style="list-style-type: none">- motor fuels which are covered by Directive 98/70/EC,- mineral oil products intended for use as fuel in mobile or fixed combustion plants,- fuels sold in closed systems (e.g. liquid gas bottles);(d) artists' paints covered by Directive 1999/45/EC;(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date.

15.2 Chemical safety assessment.

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

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SECTION 16: OTHER INFORMATION.

Complete text of the H phrases that appear in section 3:

H314	Causes severe skin burns and eye damage.
H331	Toxic if inhaled.
H351	Suspected of causing cancer.
H360D	May damage fertility or the unborn child.

Classification codes:

Acute Tox. 3 : Acute toxicity (Inhalation), Category 3
Carc. 2 : Carcinogen, Category 2
Repr. 1B : Reproductive toxicant, Category 1B
STOT RE 2 : Specific target organ toxicity following a repeated exposure, Category 2
Skin Corr. 1A : Skin Corrosive, Category 1A

Changes regarding to the previous version:

- Change in the emergency number (SECTION 1.4).
- Change in the classification of the substance and label elements (SECTION 2.1 and 2.2).
- Change in the composition of the mixture (SECTION 3.2).
- Modification in fire-fighting measures (SECTION 5.2).
- Modifications in handling and storage precautions (SECTION 7.2).
- Modification of exposure data (SECTION 8.1).
- Modifications of personal protective equipment (SECTION 8.2).
- Modification in the values of the physicochemical properties (SECTION 9).
- Changes in toxicological information (SECTION 11).
- Change in bioaccumulation potential (SECTION 12.3).
- Added other adverse effects section in ecological information (SECTION 12.7).
- Modification of the ADR/IMDG/ICAO/IATA/RID classification (section 14.5).
- National legislative changes (SECTION 15.1).
- Modifications to SECTION 16.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Abbreviations and acronyms used:

BCF:	Bioconcentration factor.
CEN:	European Committee for Standardization.
DMEL:	Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.
DNEL:	Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.
EC50:	Half maximal effective concentration.
PPE:	Personal protection equipment.
LC50:	Lethal concentration, 50%.
LD50:	Lethal dose, 50%.
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) 2020/878.
Regulation (EC) No 1907/2006.
Regulation (EC) No 1272/2008.

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The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

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) 2020/878)

GVS-NP-MM-Genvinset HLA Narcolepsy Master Mix



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

1.1 Product identifier.

Product Name: Genvinset HLA Narcolepsy Master Mix
Product Code: GVS-NP-MM

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

Reaction mixture for the detection of HLA alleles DQB1*06:02 by real-time PCR 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
City: 50011 - Zaragoza
Province: Zaragoza
Telephone: (+34) 976 094 603
E-mail: info@bdrdiagnostics.com
Web: <http://www.bdrdiagnostics.com/>

1.4 Emergency telephone number: (+34) 976 094 603 (Only available during office hours; Monday-Friday; 08:30-17:30)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

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

2.2 Label elements.

The product is not classified as dangerous according to Regulation No 1272/2008 on classification, labelling and packaging of substances and mixtures and its subsequent amendments.

2.3 Other hazards.

Identifiers	Name	PBT,vPvB or endocrine disrupting properties substances (concentration $\geq 0,1\%$)
CAS No: 9036-19-5	Polyethylene glycol mono [4-(1,1,3,3-tetramethylbutyl) phenyl] ether	Substance with endocrine disrupting properties.

The mixture does not contain substances classified as PBT.

The mixture does not contain substances classified as vPvB.

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:

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GVS-NP-MM-Gevinset HLA Narcolepsy Master Mix



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Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 9036-19-5	[6] [7] Polyethylene glycol mono [4-(1,1,3,3-tetramethylbutyl) phenyl] ether	0 - 1 %	Acute Tox. 4, H302 - Aquatic Chronic 3, H412 - Eye Dam. 1, H318	-

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

[6] Substance included in the list established under Article 59, paragraph 1, REACH (Subject to authorization substance).

[7] Substance included in the list established under Article 59, paragraph 1, REACH (Substances identified as having endocrine disrupting properties).

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.

If breathing stops, seek emergency medical attention. 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 substance or mixture.

Special risks.

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.

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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.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

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.

The product does not require special storage measures. 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 the containers between -30 and -18 °C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

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:

Concentration:	100 %
Uses:	Reaction mixture for the detection of HLA alleles DQB1*06:02 by real-time PCR with TaqMan® hydrolysis probes.
Breathing protection:	
	If the recommended technical measures are observed, no individual protection equipment is necessary.
Hand protection:	
PPE:	Disposable laboratory gloves

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Characteristics:	Powder-free nitrile or latex gloves. They prevent contamination of hands with biological and chemical fluids, but they do not prevent punctures and needlestick injuries.		
CEN standards:	EN 374-1, En 374-2, En 374-4, En 374-5, EN 420-EN, 16523-1:2015		
Maintenance:	They should be stored in cool, dark places without being exposed to direct sunlight, fluorescent lights, X-rays, ozone and moisture.		
Observations:	The gloves should be the correct size, and fit the hand without being too loose or too tight. They should always be used with clean and dry hands.		
Material:	Latex	Breakthrough time (min.):	> 30
			Material thickness (mm):
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.

Physical state: Liquid

Colour: Colourless

Odour: Odourless

Odour threshold: Not available (not known).

Melting point: 0 °C (Pour point (ASTM D 9766))

Freezing point: 0 °C (Methods of freezing temperature (BS 4695))

Boiling point or initial boiling point and boiling range: 100 °C (Estimations in base on the Regulation (CE) N°1272 / 2008 indications.)

Flammability: Not available (Not relevant for this type of product).

Lower explosion limit: 0,9% (Determination of the explosion limits and the limiting oxygen concentration (LOC) for flammable gases and vapours. (UNE-EN 1839:2017))

Upper explosion limit: 0,0% (Determination of the explosion limits and the limiting oxygen concentration (LOC) for flammable gases and vapours. (UNE-EN 1839:2017))

Flash point: Not available due to the nature/properties of the product

Auto-ignition temperature: Not available (not known).

Decomposition temperature: Not available (not known).

pH: 7-8 (pH Meter/potentiometric/electrometric method)

Kinematic viscosity: Not available (not known).

Solubility: Not available (not known).

Hydrosolubility: Water-soluble (Fully mixable)

Liposolubility: Not available (not known).

Partition coefficient n-octanol/water (log value): Not applicable (Does not apply to mixtures).

Vapour pressure: Not available (not known).

Absolute density: 1100 kg/m³ (calculation/estimation)

Relative density: 1,1 (Pycnometer (ISO 758))

Relative vapour density: Not available (not known).

Particle characteristics: Not applicable (Applies to solids only).

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9.2 Other information

Other safety characteristics

Formation of explosible dust/air mixtures:

The particle characteristics to which the data apply: Se aplica únicamente a los sólidos

Viscosity: Not available due to the nature/properties of the product

Dropping point: Not available due to the nature/properties of the product

Blink: Not available due to the nature/properties 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 hazard classes as defined in Regulation (EC) N° 1272/2008.

There are no tested data available on the product.

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

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

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.

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j) aspiration hazard;
Not conclusive data for classification.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

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 Endocrine disrupting properties.

Substances with endocrine disrupting properties can cause in living organisms: hormone imbalance, decrease in the quality and quantity of gametes, fertility problems, alteration of reproductive behaviors, deformation of sexual organs, embryonic abnormalities, changes in the sex ratio of a species and / or developmental delays.

12.7 Other adverse effects.

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.

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.

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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 or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: 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.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION.

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

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.

Complete text of the H phrases that appear in section 3:

H302	Harmful if swallowed.
H318	Causes serious eye damage.
H412	Harmful to aquatic life with long lasting effects.

Classification codes:

Acute Tox. 4 : Acute toxicity (Oral), Category 4

Aquatic Chronic 3 : Chronic effect to the aquatic environment, Category 3

Eye Dam. 1 : Serious eye damage, Category 1

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Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

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) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

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.

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

1.1 Product identifier.

Product Name: Gevinset HLA Narcolepsy Positive Control
Product Code: GVS-NP-C+

1.2 Relevant identified uses of the substance or 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
City: 50011 - Zaragoza
Province: Zaragoza
Telephone: (+34) 976 094 603
E-mail: info@bdrdiagnostics.com
Web: <http://www.bdrdiagnostics.com/>

1.4 Emergency telephone number: (+34) 976 094 603 (Only available during office hours; Monday-Friday; 08:30-17:30)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

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

2.2 Label elements.

The product is not classified as dangerous according to Regulation No 1272/2008 on classification, labelling and packaging of substances and mixtures and its subsequent amendments.

2.3 Other hazards.

The mixture does not contain substances classified as PBT.
The mixture does not contain substances classified as vPvB.
The mixture does not contain any endocrine disrupting properties substances.

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 at a concentration higher than the values established in Annex II of Regulation (EC) 1907/2006 and its subsequent modifications, which represent a danger to health or the environment, neither have a limit of Community exposure in the workplace, neither are classified as PBT / vPvB, neither are they on the candidate list.

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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.

If breathing stops, seek emergency medical attention. 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 substance or mixture.

Special risks.

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.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

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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.

The product does not require special storage measures. 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 the containers between -30 and -18 °C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

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:

Concentration:	100 %
Uses:	Evaluate test validity.
Breathing protection:	
If the recommended technical measures are observed, no individual protection equipment is necessary.	
Hand protection:	
PPE:	Disposable laboratory gloves
Characteristics:	Powder-free nitrile or latex gloves. They prevent contamination of hands with biological and chemical fluids, but they do not prevent punctures and needlestick injuries.
CEN standards:	EN 374-1, En 374-2, En 374-4, En 374-5, EN 420-EN, 16523-1:2015
Maintenance:	They should be stored in cool, dark places without being exposed to direct sunlight, fluorescent lights, X-rays, ozone and moisture.
Observations:	The gloves should be the correct size, and fit the hand without being too loose or too tight. They should always be used with clean and dry hands.
Material:	Latex
Breakthrough time (min.):	> 30
Material thickness (mm):	
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

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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.

Physical state: Liquid

Colour: Colourless

Odour: Odourless

Odour threshold: Not available (not known).

Melting point: 0 °C (Pour point (ASTM D 9766))

Freezing point: 0 °C (Methods of freezing temperature (BS 4695))

Boiling point or initial boiling point and boiling range: 100 °C (Estimations in base on the Regulation (CE) N°1272 / 2008 indications.)

Flammability: Not available (Not relevant for this type of product).

Lower explosion limit: Not available due to the nature/properties of the product

Upper explosion limit: Not available due to the nature/properties of the product

Flash point: Not available due to the nature/properties of the product

Auto-ignition temperature: Not available (not known).

Decomposition temperature: Not available (not known).

pH: 7-8 (pH Meter/potentiometric/electrometric method)

Kinematic viscosity: Not available (not known).

Solubility: Not available (not known).

Hydrosolubility: Water-soluble (Fully mixable)

Liposolubility: Not available (not known).

Partition coefficient n-octanol/water (log value): Not applicable (Does not apply to mixtures).

Vapour pressure: Not available (not known).

Absolute density: 1000 kg/m³ (calculation/estimation)

Relative density: 1 (Pycnometer (ISO 758))

Relative vapour density: Not available (not known).

Particle characteristics: Not applicable (Applies to solids only).

9.2 Other information

Other safety characteristics

Viscosity: Not available due to the nature/properties of the product

Dropping point: Not available due to the nature/properties of the product

Blink: Not available due to the nature/properties 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.

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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 hazard classes as defined in Regulation (EC) N° 1272/2008.

There are no tested data available on the product.

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.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

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.

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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 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

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.
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.

14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: 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.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

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(in accordance with Regulation (EU) 2020/878)

GVS-NP-C+-Genvinset HLA Narcolepsy Positive Control

Version 03 Date of compilation: 20/04/2020

Version 04 (replaces version 03)

Revision date: 14/08/2023



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SECTION 15: REGULATORY INFORMATION.

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

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.

Changes regarding to the previous version:

- Change in the emergency number (SECTION 1.4).
- Modification in fire-fighting measures (SECTION 5.2).
- Modifications to handling and storage precautions (SECTION 7.2).
- Modifications of the personal protective equipment (SECTION 8.2).
- Modification in the values of the physical and chemical properties (SECTION 9)
- Change in the hazard classification (SECTION 11).
- Added other adverse effects section in ecological information (SECTION 12.7).
- Modification of the classification ADR/IMDG/ICAO/IATA/RID (SECTION 14.5).
- National legislative changes (SECTION 15.1).
- Modifications to SECTION 16.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

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) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

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.

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(in accordance with Regulation (EU) 2020/878)



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Version 03 Date of compilation: 20/04/2020

Version 04 (replaces version 03)

Revision date: 26/07/2023

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/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 substance or 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 Pilón 86, Casa 7 Local
City: 50011 - Zaragoza
Province: Zaragoza
Telephone: (+34) 976 094 603
E-mail: info@bdrdiagnostics.com
Web: <http://www.bdrdiagnostics.com/>

1.4 Emergency telephone number: (+34) 976 094 603 (Only available during office hours; Monday-Friday; 08:30-17:30)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

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

2.2 Label elements.

The product is not classified as dangerous according to Regulation No 1272/2008 on classification, labelling and packaging of substances and mixtures and its subsequent amendments.

2.3 Other hazards.

The mixture does not contain substances classified as PBT.
The mixture does not contain substances classified as vPvB.
The mixture does not contain any endocrine disrupting properties substances.

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 at a concentration higher than the values established in Annex II of Regulation (EC) 1907/2006 and its subsequent modifications, which represent a danger to health or the environment, neither have a limit of Community exposure in the workplace, neither are classified as PBT / vPvB, neither are they on 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.

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Inhalation.

If breathing stops, seek emergency medical attention. 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 substance or mixture.

Special risks.

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.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

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.

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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.

The product does not require special storage measures. 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 the containers between -30 and -18 °C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

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:

Concentration:	100 %
Uses:	Contamination control.
Breathing protection:	
If the recommended technical measures are observed, no individual protection equipment is necessary.	
Hand protection:	
PPE:	Disposable laboratory gloves
Characteristics:	Powder-free nitrile or latex gloves. They prevent contamination of hands with biological and chemical fluids, but they do not prevent punctures and needlestick injuries.
CEN standards:	EN 374-1, En 374-2, En 374-4, En 374-5, EN 420-EN, 16523-1:2015
Maintenance:	They should be stored in cool, dark places without being exposed to direct sunlight, fluorescent lights, X-rays, ozone and moisture.
Observations:	The gloves should be the correct size, and fit the hand without being too loose or too tight. They should always be used with clean and dry hands.
Material:	Latex
Breakthrough time (min.):	> 30
Material thickness (mm):	
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.

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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.

Physical state: Liquid

Colour: Colourless

Odour: Odourless

Odour threshold: Not available (not known).

Melting point: 0 °C (Pour point (ASTM D 9766))

Freezing point: 0 °C (Methods of freezing temperature (BS 4695))

Boiling point or initial boiling point and boiling range: 100 °C (Estimations in base on the Regulation (CE) N°1272 / 2008 indications.)

Flammability: Not applicable (Not relevant for this type of product)

Lower explosion limit: Not available due to the nature/properties of the product

Upper explosion limit: Not available due to the nature/properties of the product

Flash point: Not available due to the nature/properties of the product

Auto-ignition temperature: Not available (not known).

Decomposition temperature: Not available (not known).

pH: 7-8 (pH Meter/potentiometric/electrometric method)

Kinematic viscosity: Not available (not known).

Solubility: Not available (not known).

Hydrosolubility: Not available (not known).

Liposolubility: Not available (not known).

Partition coefficient n-octanol/water (log value): Not applicable (Not relevant for this type of product)

Vapour pressure: 2300 Pa (Estimations in base on the Regulation (CE) N°1272 / 2008 indications.)

Absolute density: 1000 kg/m³ (calculation/estimation)

Relative density: 1 (Pycnometer (ISO 758))

Relative vapour density: Not available (not known).

Particle characteristics: Not applicable (Applies to solids only).

9.2 Other information

Other safety characteristics

Viscosity: Not available due to the nature/properties of the product

Dropping point: Not available due to the nature/properties of the product

Blink: Not available due to the nature/properties 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 (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.

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SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

There are no tested data available on the product.

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.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

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.

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12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

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.

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.

14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: 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.

Transport by ship, FEM – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION.

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

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.

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SECTION 16: OTHER INFORMATION.

Changes regarding to the previous version:

- Change in the emergency telephone (SECTION 1.4).
- Modification in fire-fighting measures (SECTION 5.2).
- Modifications to handling and storage precautions (SECTION 7.2).
- Modifications to personal protective equipment (SECTION 8.2).
- Modification in the values of the physicochemical properties (SECTION 9).
- Change in hazard classification (SECTION 11.1).
- Added other adverse effects section in ecological information (SECTION 12.7).
- Modification of the ADR/IMDG/ICAO/IATA/RID classification (section 14.5).
- National legislative changes (SECTION 15.1).
- Modifications to SECTION 16.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

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>

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Regulation (EU) 2020/878.

Regulation (EC) No 1907/2006.

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