

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

1.1 Product identifier

Product name : Yumizen G DDi 2 - R1
SAP Code : 1300036391
Product is part of kit : 1300036391
Product description : 3 X 6.5 mL
Product type : Liquid.

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

Diagnostic reagent for quantitative *in vitro* determination of D-dimer in plasma.

1.3 Details of the supplier of the safety data sheet

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
BP 7290
34184 MONTPELLIER CEDEX 4 - FRANCE
Tel: +33 (0) 4 67 14 15 16
Fax: +33 (0) 4 67 14 15 17

e-mail address of person responsible for this SDS : documentation.med@horiba.com

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number : +44 (0)20 7771 5310

Supplier

Telephone number : + 800 67 14 15 16

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

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

Skin Sens. 1, H317
Carc. 1A, H350i (inhalation)
Repr. 1B, H360D (Unborn child)
STOT RE 2, H373
Aquatic Chronic 3, H412

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms :



Signal word : Danger

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SECTION 2: Hazards identification

- Hazard statements** : May cause an allergic skin reaction.
May cause cancer by inhalation.
May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.
Harmful to aquatic life with long lasting effects.
- Precautionary statements**
- Prevention** : Obtain special instructions before use.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection/face protection.
- Response** : IF ON SKIN: Wash with plenty of soap and water.
IF exposed or concerned: Get medical attention.
Take off contaminated clothing and wash it before reuse.
- Storage** : Store locked up.
- Disposal** : Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Hazardous ingredients** : nickel sulfate
- Supplemental label elements** : Not applicable.
- Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Restricted to professional users.

2.3 Other hazards

- Other hazards which do not result in classification** : None known.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mixture

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Type
nickel sulfate	EC: 232-104-9 CAS: 7786-81-4 Index: 028-009-00-5	<1	Acute Tox. 4, H302 Acute Tox. 4, H332 Skin Irrit. 2, H315 Resp. Sens. 1, H334 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1A, H350i (inhalation) Repr. 1B, H360D (Unborn child) STOT RE 1, H372 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1)	[1] [2]
sodium azide	EC: 247-852-1 CAS: 26628-22-8 Index: 011-004-00-7	<0,1	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1,	[1] [2]

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SECTION 3: Composition/information on ingredients

			H410 (M=1) EUH032 See Section 16 for the full text of the H statements declared above.
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There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern
- [6] Additional disclosure due to company policy

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

- Eye contact** : No specific data.

SECTION 4: First aid measures

- Inhalation** : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
reduced foetal weight
increase in foetal deaths
skeletal malformations
- Ingestion** : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

5.2 Special hazards arising from the substance or mixture

- Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst. This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
- Hazardous combustion products** : No specific data.

5.3 Advice for firefighters

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

SECTION 6: Accidental release measures

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

Other information : This preparation contains a small amount of sodium azide. Sodium azide is harmful to aquatic organisms and can react with copper, lead, brass or solder in plumbing system and form potentially explosive metal azides. Prevent preparation from entering the drain and water intakes in the environment. If preparation enters the drain, flush with large amounts of water to prevent azide build up. Follow proper disposal procedures.

6.3 Methods and material for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product.

6.4 Reference to other sections : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not breathe vapour or mist. Do not ingest. Avoid release to the environment. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

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SECTION 7: Handling and storage

Store between the following temperatures: 2 to 8°C (35,6 to 46,4°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Recommendations : Due to sodium azide, incompatible with acid and some metals. Forms explosion-sensitive compounds.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
nickel sulfate	EH40/2005 WELs (United Kingdom (UK), 12/2011). Absorbed through skin. Inhalation sensitiser. TWA: 0,1 mg/m ³ , (as Ni) 8 hours.
sodium azide	EH40/2005 WELs (United Kingdom (UK), 12/2011). Absorbed through skin. STEL: 0,3 mg/m ³ , (as NaN ₃) 15 minutes. TWA: 0,1 mg/m ³ , (as NaN ₃) 8 hours.

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Individual protection measures

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SECTION 8: Exposure controls/personal protection

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use. Recommended: Combination filtering device (DIN EN 141)
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- Physical state** : Liquid.
- Colour** : Colourless.
- Odour** : Odourless.
- Odour threshold** : Not available.
- pH** : 6,7 to 7,7
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability** : May be combustible at high temperature.
- Upper/lower flammability or explosive limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.

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SECTION 9: Physical and chemical properties

Relative density	: Not available.
Solubility(ies)	: Easily soluble in the following materials: cold water and hot water.
Partition coefficient: n-octanol/ water	: Not available.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Explosive properties	: Not available.
Oxidising properties	: Not available.

9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: The product is stable.
10.3 Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	: No specific data.
Recommendations	: This reagent contains sodium azide as preservative. Sodium azide may react with Pb and Cu and form dangerous material, metal azide product.
10.5 Incompatible materials	: No specific data.
Other information	: Keep away from the following materials: Flammable material
10.6 Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
sodium azide	LD50 Oral	Rat	27 mg/kg	-

Acute toxicity estimates

Not available.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
nickel sulfate	Skin - Mild irritant	Woman	-	48 hours 5 Percent	-

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

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SECTION 11: Toxicological information

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Product/ingredient name	Category	Route of exposure	Target organs
nickel sulfate	Category 1	Not determined	Not determined

Aspiration hazard

Not available.

Information on likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : May cause an allergic skin reaction.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations

Skin contact : Adverse symptoms may include the following:
irritation
redness
reduced foetal weight
increase in foetal deaths
skeletal malformations

Ingestion : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

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SECTION 11: Toxicological information

Potential delayed effects : Not available.

Potential chronic health effects

Conclusion/Summary : Not available.

General : May cause damage to organs through prolonged or repeated exposure. Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity : May cause cancer by inhalation. Risk of cancer depends on duration and level of exposure.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : May damage the unborn child.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
nickel sulfate	Acute IC50 7,28 mg/l Marine water	Algae - Phaeodactylum tricornutum - Exponential growth phase	72 hours
	Acute IC50 4,59 mg/l Marine water	Algae - Phaeodactylum tricornutum - Exponential growth phase	96 hours
	Acute LC50 39177,81 µg/l Fresh water	Crustaceans - Stenocypris major - Adult	48 hours
sodium azide	Acute LC50 180 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 589,9 µg/l Fresh water	Fish - Danio rerio - Larvae	96 hours
	Acute EC50 0,348 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata	96 hours
	Acute EC50 6,4 mg/l Fresh water	Crustaceans - Simocephalus serrulatus - Larvae	48 hours
	Acute EC50 4,2 mg/l Fresh water	Daphnia - Daphnia pulex - Larvae	48 hours
	Acute LC50 0,68 mg/l Fresh water	Fish - Lepomis macrochirus	96 hours
	Chronic NOEC 5600 µg/l Marine water	Algae - Macrocyctis pyrifera	96 hours

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
nickel sulfate	-	5613	high

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

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SECTION 12: Ecological information

- PBT** : Not applicable.
vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

- Methods of disposal** : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

- Hazardous waste** : The classification of the product may meet the criteria for a hazardous waste.

Packaging

- Methods of disposal** : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

- Special precautions** : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

- 14.6 Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions : Restricted to professional users.
on the manufacture,
placing on the market
and use of certain
dangerous substances,
mixtures and articles

Other EU regulations

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

Biocidal products regulation : Not applicable.

Product/ingredient name	List name	Name on list	Classification	Notes
nickel sulfate	UK Occupational Exposure Limits EH40 - WEL	inorganic nickel compounds Soluble in water	Carc.	-

MAL-code Not applicable.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : All components are listed or exempted.

Canada : All components are listed or exempted.

China : All components are listed or exempted.

Europe : All components are listed or exempted.

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SECTION 15: Regulatory information

Japan	: Japan inventory (ENCS): All components are listed or exempted. Japan inventory (ISHL): Not determined.
Malaysia	: Not determined.
New Zealand	: All components are listed or exempted.
Philippines	: All components are listed or exempted.
Republic of Korea	: All components are listed or exempted.
Taiwan	: All components are listed or exempted.
Thailand	: Not determined.
Turkey	: Not determined.
United States	: All components are listed or exempted.
Viet Nam	: Not determined.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Revision comments : New MSDS form.

✔ Indicates information that has changed from previously issued version.

Abbreviations and acronyms :

- ATE = Acute Toxicity Estimate
- CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
- DMEL = Derived Minimal Effect Level
- DNEL = Derived No Effect Level
- EUH statement = CLP-specific Hazard statement
- PBT = Persistent, Bioaccumulative and Toxic
- PNEC = Predicted No Effect Concentration
- RRN = REACH Registration Number
- vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Skin Sens. 1, H317 Carc. 1A, H350i (inhalation) Repr. 1B, H360D (Unborn child) STOT RE 2, H373 Aquatic Chronic 3, H412	Calculation method Expert judgment Calculation method Calculation method Calculation method

Full text of abbreviated H statements

H300	Fatal if swallowed.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341	Suspected of causing genetic defects.
H350i (inhalation)	May cause cancer by inhalation.
H360D	May damage the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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SECTION 16: Other information

[Full text of classifications \[CLP/GHS\]](#)

Acute Tox. 2, H300	ACUTE TOXICITY (oral) - Category 2
Acute Tox. 4, H302	ACUTE TOXICITY (oral) - Category 4
Acute Tox. 4, H332	ACUTE TOXICITY (inhalation) - Category 4
Aquatic Acute 1, H400	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1, H410	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Aquatic Chronic 3, H412	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3
Carc. 1A, H350i (inhalation)	CARCINOGENICITY (inhalation) - Category 1A
EUH032	Contact with acids liberates very toxic gas.
Muta. 2, H341	GERM CELL MUTAGENICITY - Category 2
Repr. 1B, H360D	REPRODUCTIVE TOXICITY (Unborn child) - Category 1B
Resp. Sens. 1, H334	RESPIRATORY SENSITISATION - Category 1
Skin Irrit. 2, H315	SKIN CORROSION/IRRITATION - Category 2
Skin Sens. 1, H317	SKIN SENSITISATION - Category 1
STOT RE 1, H372	SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE - Category 1
STOT RE 2, H373	SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE - Category 2

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To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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

1.1 Product identifier

Product name	: Yumizen G DDi 2 - R2
SAP Code	: 1300036391
Product is part of kit	: 1300036391
Product description	: 3 X 2.5 mL
Product type	: Liquid.

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

Diagnostic reagent for quantitative *in vitro* determination of D-dimer in plasma.

1.3 Details of the supplier of the safety data sheet

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
BP 7290
34184 MONTPELLIER CEDEX 4 - FRANCE
Tel: +33 (0) 4 67 14 15 16
Fax: +33 (0) 4 67 14 15 17

e-mail address of person responsible for this SDS : documentation.med@horiba.com

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number : +44 (0)20 7771 5310

Supplier

Telephone number : + 800 67 14 15 16

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

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

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Supplemental label elements : Not applicable.

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SECTION 2: Hazards identification

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

2.3 Other hazards

Other hazards which do not result in classification : None known.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mixture

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

5.2 Special hazards arising from the substance or mixture

- Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst.
- Hazardous combustion products** : No specific data.

5.3 Advice for firefighters

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

- Other information** : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
- Other information** : This preparation contains a small amount of sodium azide. Sodium azide is harmful to aquatic organisms and can react with copper, lead, brass or solder in plumbing system and form potentially explosive metal azides. Prevent preparation from entering the drain and water intakes in the environment. If preparation enters the drain, flush with large amounts of water to prevent azide build up. Follow proper disposal procedures.

6.3 Methods and material for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor.

SECTION 6: Accidental release measures

- 6.4 Reference to other sections** : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store between the following temperatures: 2 to 8°C (35,6 to 46,4°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

- Recommendations** : Due to sodium azide, incompatible with acid and some metals. Forms explosion-sensitive compounds.

7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

- Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

SECTION 8: Exposure controls/personal protection

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- Physical state** : Liquid.
- Colour** : White.
- Odour** : Odourless.
- Odour threshold** : Not available.
- pH** : 8,5 to 9,5
- Melting point/freezing point** : Not available.
- Initial boiling point and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability** : May be combustible at high temperature.

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SECTION 9: Physical and chemical properties

Upper/lower flammability or explosive limits	: Not available.
Vapour pressure	: Not available.
Vapour density	: Not available.
Relative density	: Not available.
Solubility(ies)	: Easily soluble in the following materials: cold water and hot water.
Partition coefficient: n-octanol/ water	: Not available.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Explosive properties	: Not available.
Oxidising properties	: Not available.

9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: The product is stable.
10.3 Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	: No specific data.
Recommendations	: This reagent contains sodium azide as preservative. Sodium azide may react with Pb and Cu and form dangerous material, metal azide product.
10.5 Incompatible materials	: No specific data.
10.6 Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No known significant effects or critical hazards.

Acute toxicity estimates

Not available.

Irritation/Corrosion

No known significant effects or critical hazards.

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

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SECTION 11: Toxicological information

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.
Ingestion : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Potential chronic health effects

Conclusion/Summary : Not available.
General : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : No known significant effects or critical hazards.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

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SECTION 11: Toxicological information

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

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SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

14.6 Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Other EU regulations

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

Biocidal products regulation : Not applicable.

MAL-code : Not applicable.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

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SECTION 15: Regulatory information

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia	: All components are listed or exempted.
Canada	: All components are listed or exempted.
China	: All components are listed or exempted.
Europe	: All components are listed or exempted.
Japan	: Japan inventory (ENCS) : All components are listed or exempted. Japan inventory (ISHL) : Not determined.
Malaysia	: Not determined.
New Zealand	: All components are listed or exempted.
Philippines	: All components are listed or exempted.
Republic of Korea	: All components are listed or exempted.
Taiwan	: All components are listed or exempted.
Thailand	: Not determined.
Turkey	: Not determined.
United States	: All components are listed or exempted.
Viet Nam	: Not determined.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Revision comments : New MSDS form.

✔ Indicates information that has changed from previously issued version.

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H statements

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SECTION 16: Other information

Not applicable.

[Full text of classifications \[CLP/GHS\]](#)

Not applicable.

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