

Safety Data Sheet (SDS)

According to Regulation (EC) No 1907/2006 (REACH), Annex II(COMMISSION REGULATION (EU) No 2020/878)

Vcheck Control D-Dimer

Date of issue: 2024-09-05 Version: 1.0 **Revision date: Not applicable** SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING 1.1. Product identifier Trade name/designation : Vcheck Control D-Dimer 1.2. Relevant identified uses of the substance or mixture and uses advised against 1.2.1. Relevant identified uses - Others 1.2.2. Uses advised against - For veterinary use only. Not for pharmaceutical, house hold or other uses 1.3. Details of the supplier of the safety data sheet Manufacturer : BIONOTE Company name Address : 22, Samsung 1-ro 4-gil, Hwaseong-si, Gyeonggi-do 18449, Republic of Korea Telephone number : +82 31 211 0516 Supplier Company name : BIONOTE Address : 22, Samsung 1-ro 4-gil, Hwaseong-si, Gyeonggi-do 18449, Republic of Korea Telephone number : +82 31 211 0516 1.4. Emergency telephone number EU-wide emergency number : 112 See section 16.6 for the list of telephone number of National Helpdesks in the European Economic Area. **SECTION 2: HAZARD IDENTIFICATION** 2.1. Classification of the substance or mixture 2.1.1. Classification according to Regulation (EC) No 1272/2008 [CLP] - Not applicable 2.2. Label elements 2.2.1. Labelling according to Regulation (EC) No 1272/2008 [CLP] * Hazard Pictogram(s) - Not applicable * Signal word : Not applicable * Hazard statement(s) -Not applicable * Precautionary statement(s) 1) Prevention -Not applicable 2) Response -Not applicable 3) Storage -Not applicable 4) Disposal -Not applicable 2.3. Other hazards - Not available **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS** 3.1. Substances - Not available

3.2. Mixtures

- All substances/weight are non-hazardous or in concentrations not to be declared.

SECTION 4: FIRST AID MEASURES

- 4.1. Description of first aid measures
 - **General notes**

- No general information.

Following inhalation

- Take specific treatment if needed.
- When exposed to large amounts of steam and mist, move to fresh air.

Following skin contact

- Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
- Wash contaminated clothing thoroughly before re-using.

Following eye contact

- Do not rub your eyes.
- Immediately flush eyes with plenty of water for at least 15 minutes and call a doctor/physician.

Following ingestion

- Please be advised by doctor whether induction of vomit is demanded or not.
- Rinse your mouth with water immediately.

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

- Not available

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

- Notify medical personnel of contaminated situations and have them take appropriate protective measures.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

- Dry chemical, carbon dioxide, regular foam extinguishing agent, spray

Unsuitable extinguishing media

- Avoid use of water jet for extinguishing

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products

- Not available

5.3. Advice for firefighters

- Avoid inhalation of materials or combustion by-products.
- Cool containers with water until well after fire is out.
- Do not approach the tank surrounded by fire until it is extinguished.
- In case of conflagration, use automatic fire sprinkler. Major fire may require withdrawal, allowing the object itself to burn.
- Keep unauthorized personnel out.
- Move containers from fire area, if you can do without the risk.
- Notify your local firestation and inform the location of the fire and characteristics hazard.
- Use appropriate extinguishing measure suitable for surrounding fire.
- Wear appropriate protective equipment.
- Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures: Not applicable
- If required, notify relevant authorities according to all applicable regulations.
- Protective equipment: Wear proper protective equipment.

6.1.2. For emergency responders

- Avoid dust formation.
- Do not touch spilled material. Stop leak if you can do it without risk.
- Handle the damaged containers or spilled material after wearing appropriate protective equipment
- Moist with water to prevent dust scattering.
- Move container to safe area from the leak area.
- Must work against the wind, let the upwind people to evacuate.
- Remove all sources of ignition.
- Ventilate closed spaces before entering.
- Wear proper personal protective apparatus as indicated in Section 8 and avoid skin contact and inhalation.

6.2. Environmental precautions

- Avoid dispersal of spilt material and runoff and contact with waterways, drains and sewers. If large spills, advise emergency services.

- If large amounts have been spilled, inform the relevant authorities.
- Prevent runoff and contact with waterways, drains or sewers.

6.3. Methods and material for containment and cleaning up

6.3.1. For containment

- Clean up all spills immediately.
- Clear area of personnel and move up wind.
- Clear spills immediately
- Control personal contact by using protective equipment.

- Don't use a brush or compressed air for cleaning surfaces or clothing.
- No smoking, flame or ignition sources.
- Prevent, by any means available, spillage from entering drains or water course.
- Stop leak if safe to do so.
- 6.3.2. For cleaning up
 - Appropriate container for disposal of spilled material collected.
 - Disposal of waste shall be in compliance with the Wastes Control Act
 - Dust spills : Cover dust spills with plastic sheet or waterproof cloth to minimize spreading and avoid contact with water.
 - Large spill : Stay upwind and keep out of low areas. Dike for later disposal.
 - Notify the central and local government if the emission reach the standard threshold.
 - Put the spilled material in an appropriate containers and clean the contaminated area
 - Small liquid state spills: Appropriate container for disposal of spilled material collected.
- 6.3.3. Other information
 - Slippery when spilt.

6.4. Reference to other sections

- See Section 13 for information on disposal.
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

- Avoid contact with incompatible materials.
- Avoid direct physical contact.
- Comply with all applicable laws and regulations for handling
- Dealing only with a well-ventilated place.
- Do not handle until all safety precautions have been read and understood.
- Get the manual before use.
- Minimize occurrence of dust and accumulation.
- Operators should wear antistatic footwear and clothing.
- Refer to Engineering controls and personal protective equipment.
- Since emptied containers retain product residue(vapor, liquid, solid) follow all MSDS and label warnings even after container is emptied.
- Wash thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

- Avoid direct sunlight.
- Check regularly for leaks.
- Do not apply any physical shock to container.
- Do not apply direct heat.
- Do not use damaged containers.
- Keep in the original container.
- Keep sealed when not in use.
- No open fire.
- Please pay attention to incompatibilities materials and conditions to avoid.
- Prevent static electricity and keep away from combustible materials or heat sources.
- Save in cool, dry and well ventilated place.
- Store according to current laws and regulations

7.3. Specific end use(s)

- See Section 1 for information on 1.2 Relevant identified uses.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

8.1.1. Occupational exposure limits

European Union (EU) Commission Directive 2006/15/EC (IOELVs) - Not available European Union (EU) Commission Directive 2006/15/EC (IOELVs) - Skin

- Not available

- Greece Occupational Exposure Limits
 - Not available

Netherlands Occupational Exposure Limits

- Not available
- Denmark Indicative List of Organic Solvents - Not available
- Denmark List of Limit Values for Dust
- Not available

Latvia Occupational Exposure Limit Values (OELV) for Chemical Substances in the Work Environment Atmosphere

- Not available

Latvia Carcinogens and their Occupational Exposure Limit Values (OELV) - Not available **Bulgaria Occupational Exposure Limits** - Not available Bulgaria Limit values for the chemical agents in the air at the working environment Not available Sweden Occupational Exposure Limit Values - Not available Sweden Occupational Exposure Limit Values and Measures against Air Contaminants Not available Spain Changes Proposed for Occupational Exposure Limit Values - Not available Spain Occupational Exposure Limit for Chemical Agents - Not available Slovak Republic Highest Admissible Exposure Limits - Not available Slovak Republic Highest Admissible Exposure Limits - Solid aerosols predominately with fibrogenic effect - Not available Slovak Republic Highest Admissible Exposure Limits - Solid aerosols with possible fibrogenic effect - Not available Slovak Republic Highest Admissible Exposure Limits - Solid aerosols predominately with nonspecific effect - Not available **Ireland Occupational Exposure Limits** - Not available UK Workplace Exposure Limits (WELs) - Not available Austria Technical Exposure Limits (TRK Values) - Not available Austria Occupational Exposure Limits - Maximum Workplace Concentrations (MAK) - Not available **Italy Occupational Exposure Limits** - Not available Czech Republic Occupational Exposure Limits (PEL and NPK-P) - Not available Czech Republic Occupational Exposure Limits - Dusts predominately with fibrogenic effect - Not available Czech Republic Occupational Exposure Limits - Dusts with possible fibrogenic effect Not available Czech Republic Occupational Exposure Limits - Dusts predominately with nonspecific effect - Not available Czech Republic Occupational Exposure Limits - Dusts predominately with irritating effect - Not available Czech Republic Occupational Exposure Limits - Mineral fibrous dusts - Not available Poland Workplace Maximum Allowable Concentration - Dust - Not available Poland Workplace Maximum Allowable Concentration - Not available France Threshold Limit Values for Occupational Exposure - VLE/VME Not available Finland Occupational Exposure Levels - Concentrations Known to be Harmful - Not available Hungary Occupational Exposure Limits Not available 8.1.2. Recommended Monitoring Procedures - 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. 8.1.3. DNEL/PNEC - Values - Not available 8.2. Exposure controls 8.2.1. Appropriate engineering controls - Business owner is recommended to maintain below recommended exposure limits for the working place with general exhaust of gas/vapour/mist/fume. 8.2.2. Individual protection measures, such as personal protective equipment Hand protection - Wear appropriate glove.

Eye protection

- Provide an emergency eye wash station and quick drench shower in the immediate work area.

- Wear primary eye protection such as splash resistant safety goggles with a secondary protection face shield.

Respiratory Protection

- Air-purifying respirator with high-efficiency particulate filtering

- Any respiratory protection with a electromotion fan(for dust, mist, fume-purifying)
- Consider warning properties before use.
- Dust, mist, fume-purifying respiratory protection

- For Unknown Concentration or Immediately Dangerous to Life or Health : Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply. Any self-contained breathing apparatus with a full facepiece.

- Respiratory protection is ranked in order from minimum to maximum.
- Self-contained breathing apparatus with a corpuscle filter of high efficiency
- Under conditions of frequent use or heavy exposure, Respiratory protection may be needed.

Skin protection

- Wear appropriate clothing.

8.2.3. Environmental exposure controls

- Do not let product enter drains. For ecological information refer to section 12.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Solid
Color	Various
Odor	Not available
pH	Not available
Melting point/Freezing point	Not available
Initial boiling point and boiling range	> 100°C
Flash point	>100°C
Evaporation rate	Not available
Flammability(solid, gas)	Not available
Upper/Lower Flammability or explosive limits	Not available
Vapour pressure	Not available
Solubility	Not available
Vapour density	Not available
Relative density	Not available
Partition coefficient of n-octanol/water	Not available
Autoignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Particle characteristics	Not available

9.2. Other information

- Not available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

- Not available

10.2. Chemical Stability

- This material is stable under recommended storage and handling conditions.

10.3. Possibility of hazardous reactions

- Hazardous Polymerization will not occur.

10.4. Conditions to avoid

- Avoid : Accumulation of electrostatic charges, Heating, Flames and hot surfaces
- Avoid contact with incompatible materials and condition.

10.5. Incompatible materials

- Not available

10.6. Hazardous decomposition products

- May emit flammable vapour if involved in fire.

SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 (a) Acute toxicity
 - Oral
 - Of al
 - Not available
 - Not available
 - Inhalation
 - Not available
 - (b) Skin corrosion/irritation
 - Not available

(c) Serious eye damage/irritation - Not available (d) Respiratory sensitization - Not available (e) Skin sensitization - Not available (f) Germ cell mutagenicity - Not available (g) Carcinogenicity - IARC - Not applicable - OSHA - Not applicable - ACGIH - Not applicable - NTP - Not applicable - EU CLP - Not applicable (h) Reproductive toxicity - Not available (i) Specific target organ toxicity(single exposure): - Not available (j) Specific target organ toxicity(repeated exposure): - Not available (k) Aspiration hazard - Not available

11.2. Information on other hazards

- Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.1. Fish

- Not available
- 12.1.2. Invertebrate
 - Not available
- 12.1.3. Algae
- Not available

12.2. Persistence and degradability

- 12.2.1. Persistence
- Not available
- 12.2.2. Degradability
- Not available
- 12.2.3. Biodegradability
 - Not available

12.3. Bioaccumulative potential

- 12.3.1. Bioaccumulation
 - Not available

12.4. Mobility in soil

- Not available

12.5. Results of PBT and vPvB assessment

- Not available

12.6. Endocrine disrupting properties

- Not available

12.7. Other adverse effects

- Not available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

- It shall be treated by incineration

- Oil water separation technology shall be applied as pre-waste treatment if it is applicable

- Stabilization and minimization treatment by incineration or similar method can be applied, if more than two kinds of designated wastes are in

mixture state and it is impractical to separate them

- Anyone with business license number who generates industrial wastes shall treat the waste by him/herself or by entrusting to the legal entities who treat the wastes, recycle the wastes of others or install and operate the waste treatment facilities according to the Wastes Control Act

- Dispose of waste in accordance with all applicable laws and regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. UN number or ID number

- Not applicable

14.2. UN proper shipping name

- Not applicable

14.3. Transport hazard class(es)

- Not applicable

14.4. Packing group (IMDG CODE/IATA DGR)

- Not applicable

14.5. Environmental hazards

- Not applicable

14.6. Special precautions for user

- Emergency Action Code
- Hazard No.(ADR)
- Local transport follows in accordance with Dangerous goods Safety Management Law.
- Package and transport follow in accordance with Department of Transportation (DOT) and other regulatory agency requirements.
- Tunnel Restriction Code
- EmS FIRE SCHEDULE : Not available
- EmS SPILLAGE SCHEDULE : Not available

14.7. Maritime transport in bulk according to IMO instruments

- Not applicable

SECTION 15: REGULATORY INFORMATION

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

15.1.1. Europe regulatory

- 15.1.1.1. REACH Restricted substance
- Not applicable
- 15.1.1.2. REACH Substances subject to authorization
- Not applicable
- 15.1.1.3. REACH SVHC
- Not applicable
- 15.1.1.4. Europe PBT
 - Not applicable
- 15.1.1.5. European Union (EU) Transport of Dangerous Goods by Road Dangerous Goods List
 - Not applicable

15.2. Chemical Safety Assessment

- Not conducted

SECTION 16: OTHER INFORMATION

16.1. Indication of changes

- The Safety Data Sheet has been reviewed and the data therein were revised and laid out according the requirements of the Commission Regulation (EU) No. 2020/878

16.2. Abbreviations and acronyms

- 1272/2008 CLP : Classification, Labelling and Packaging regulation.
- REACH : Registration, Evaluation and authorisation of chemical substances.
- DNEL : Derive no effects level
- PNEC : Predicted no effect concentration

16.3. Key literature references and sources for data

- This Safety Data Sheet was compiled with data and information from the following sources: RTECS, ECOSAR, HSDB, SIDS SIAP, ChemWATCH, CESAR, Chemical DB

16.4. Classification procedure

- The mixture classification has been derived based on the classification of the individual components in accordance with the rules set out in Regulation (EC) No 1272/2008 (CLP) as well as the translation tables in Annex VII to the same regulation.

16.5. Training advice

- Not applicable

16.6. Further information

- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

- This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only.

- It should not therefore be construed as guaranteeing any specific property of the product.

- Contact National Helpdesks, List of Telephone Numbers :

AUSTRIA (Vienna Wien) +43 1 515 61 0, BELGIUM (Brussels Bruxelles) +32 070 245 245, BULGARIA (Sofia) +359 2 9888 205, Croatia +385 1 2348 342 CZECH REPUBLIC (Prague Praha) +420 224 919 293 or +420 224 915 402, DENMARK (Copenhagen) 82 12 12 12, ESTONIA (Tallinn) 112, FINLAND (Helsinki) +358 9 471 977, FRANCE (Paris) +33 1 45 42 59 59, GERMANY (Berlin) +49 30 19240, GREECE (Athens Athinai) +30 210 77 93 777, HUNGARY (Budapest) +36 80 201 199, ICELAND (Reykjavik) +354 543 2222 or 112, IRELAND (Dublin) +353 1 8379964 or +353 1 809 2166, ITALY (Rome) +39 06 305 4343, LATVIA (Riga) 112 or +371 6704 2473, LITHUANIA (Vilnius) +370 5 236 20 52 or +370 687 53378, Luxembourg +352 70 245 245, MALTA +356 2122 4071, NETHERLANDS (Bilthoven) +31 30 274 88 88, NORWAY (Oslo) 22 591300, POLAND (Gdansk) +48 58301 65 16 or +48 58 349 2831, PORTUGAL (Lisbon Lisboa) 808 250 143, ROMANIA (Bucharest) +40 21 3183606 SLOVAKIA (Bratislava) +421 2 54 77 4166, SLOVENIA (Ljubljana) + 386 41 650 500, SPAIN +34 91 562 04 20(spanish language) or +34 91 768 98 00(You can request to be served in English), SWEDEN (Stockholm) 112 or +46 10 456 6700 (mon-fri 9.00-17.00), UNITED KINGDOM (London) 112 or 0845 4647 (NHS Direct).