

SAFETY DATA SHEET

Safety data sheet according to regulation (EC) No. 1907/2006 (REACH)

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

1. Product identifier and company identifier

Product name	Inherited CardioKitDx
Product reference	IMG-390
Reactions	16 rxn
Intended use	For <i>in vitro</i> diagnostic use only

Supplier information:

Health in Code, S.L.

Calle de la Travesía s/n, 15E Base 5, Valencia, 46024,
Spain.

<http://www.healthincode.com>

National Institute of Toxicology

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2. Hazards identification

Classification of the substance or mixture:

- Classification according to Regulation (EC) No. 1272/2008 [CLP/GHP]:

Reagent/Ingredient	Classification	Description of hazards	Category
Fragmentation Buffer	H361	Reproductive toxicant	Category 2
Fragmentation Enzyme	H320	Causes eye irritation	Category 2B
Beads and Buffers Plate			
Beads	H315	Skin corrosion/irritation	Category 2
	H319	Serious eye damage/irritation	Category 2

	H317	Skin sensitisation	Category 1
	H411	Chronic (long-term) aquatic hazard	Category 2
Ethanol	H225	Flammable liquids	Category 2
	H319	Serious eye damage/irritation	Category 2

Ingredients of unknown toxicity:

- Fragmentation Buffer:
 - Percentage of the mixture that consists of ingredient(s) with unknown acute dermal toxicity: 1-10%.
 - Percentage of the mixture that consists of ingredient(s) with unknown acute inhalation toxicity: 1-10%.
 - Contains 2.5% ingredients of unknown aquatic environmental toxicity.
- Fragmentation Enzyme:
 - Percentage of the mixture that consists of ingredient(s) with unknown acute inhalation toxicity: 30-60%.

Label elements:

- Fragmentation Buffer:



- Beads and Buffers Plate:



Signal words:

- Fragmentation Buffer:
 - Warning
- Fragmentation Enzyme:
 - Warning
- Beads and Buffers Plate:
 - Warning
 - Danger

Precautionary statements:

- PREVENTION:
 - Fragmentation Buffer:
 - P201→ Obtain special instructions before use.
 - P280→ Wear protective gloves. Wear eye protection/face protection.
 - Beads and Buffers Plate:
 - P280→ Wear protective gloves. Wear eye protection/face protection.
 - P273→ Avoid release to the environment.
 - P261→ Avoid breathing vapours.
 - P264→ Wash thoroughly after handling.
 - P210→ Keep away from heat/sparks/open flames/hot surfaces and other ignition sources
No smoking.
- RESPONSE:
 - Fragmentation Buffer:
 - P308 + P313→ If exposed or concerned: Get medical advice/attention.
 - Fragmentation Enzyme:
 - P305 + P351 + P338→ If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P337 + P313→ If eye irritation persists: get medical advice/attention.
 - Beads and Buffers Plate:
 - P391→ Collect spillage.
 - P305 + P351 + P338→ If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P337 + P313→ If eye irritation persists: get medical advice/attention.
- DISPOSAL:
 - Fragmentation Buffer:
 - P501→ Dispose of contents/container in accordance with local/regional/national/international regulation.
 - Beads and Buffers Plate:
 - P501→ Dispose of contents/container in accordance with local/regional/national/international regulation.

Other hazards:

- HAZARDOUS INGREDIENTS:
 - Beads and Buffers Plate:

Mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

The remaining product components and/or ingredients have not been determined to contain persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances

3. Composition/information on ingredients

- **Substance/mixture**
 - **Fragmentation Buffer:** MIXTURE
 - **Fragmentation Enzyme:** MIXTURE
 - **Beads and Buffers Plate:** MIXTURE
 - **Reagent Plate:** MIXTURE
 - **Index strip:** MIXTURE
 - **Elution buffer:** MIXTURE
 - **Cardiovascular Probes Strip:** MIXTURE

Reagent/Ingredient	(%)	Identifiers	Classification	Specific concentration limits, M-factors, and ATE	Type*
Fragmentation Buffer					
Caesium chloride	>2.5	CAS: 7647-17-8	-	-	-
Fragmentation Enzyme					
Glycerol	≥50- ≤75	CAS: 56-81-5	-	-	-
Reagent Plate					
Glycerol	≤3	CAS: 56-81-5 REACH: Annex V CE: 200-289-5	Not classified	-	[2]
Beads and Buffers Plate					
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	<0.25	55965-84-9	Acute Tox. 3, H301 Acute Tox. 2, H310 Acute Tox. 2, H330 Skin corr. 1C, H314	ATE[Oral]= 53 mg/kg ATE[Dermal]= 87.12 mg/kg ATE [Inhal.]= 0.5 mg/l Skin corr. 1C	[1]

			Aquatic Acute 1, H400	H314: ≥0.6%	
				Skin irrit.2, H315: 0.06%≤C<0.6%	
			Aquatic Chronic 1, H410	Skin sens.1, H317:C≥0.0015%	
			EUH071	M[Acute]=100	
				M[Chronic]=100	
Ethanol	≥50- ≤75	CAS: 64-17-5 CE: 200-578-6 Index: 603-002- 00-5	Flam. Liq. 2, H225 Eye Irrit. 2, H319	-	[1], [2]

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

*Type: [1] Substance classified as hazardous to health or the environment

[2] Substance with an occupational exposure limit

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

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

4. First aid measures

▪ Eye contact:

- Fragmentation Buffer: immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses and continue rinsing for at least 10 minutes. Get medical attention if irritation persists.
- Fragmentation Buffer: immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses and continue rinsing for at least 10 minutes. Get medical attention if irritation persists.
- Reagent Plate: 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.
- Index strip: 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.
- Beads and Buffers Plate: immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue rinsing for at least 10 minutes and get medical attention.

- Cardiovascular Probes Strip: No known significant effects or critical hazards.
- Elution buffer: Check for and remove any contact lenses. Protect the undamaged eye. Flush eye with plenty of water for at least 15 minutes and get medical attention.

- **Inhalation:**
 - Fragmentation Buffer: Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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 and loosen tight clothing such as a collar, tie, belt or waistband.
 - Fragmentation Enzyme: Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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 and loosen tight clothing such as a collar, tie, belt or waistband.
 - Reagent Plate: remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if experiencing symptoms.
 - Index strip: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if experiencing symptoms.
 - Beads and Buffers Plate: remove victim to fresh air and keep at rest in a position comfortable for breathing. 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 adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Ensure sufficient supply of air. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.
 - Elution buffer: Remove victim to fresh air. Get medical attention if symptoms persist.

- **Skin contact:**
 - Fragmentation Buffer: Rinse contaminated skin with plenty of water. Remove all

contaminated clothing and footwear. Continue rinsing for at least 10 minutes and get medical attention. Wash contaminated clothing before reuse. Clean footwear thoroughly before reuse.

- Fragmentation Enzyme: Rinse contaminated skin with plenty of water. Remove all contaminated clothing and footwear. Continue rinsing for at least 10 minutes and get medical attention. Wash contaminated clothing before reuse. Clean footwear thoroughly before reuse.
- Reagents Plate: Rinse contaminated skin with plenty of water. Remove all contaminated clothing and footwear. Get medical attention if experiencing symptoms.
- Index Strip: Rinse contaminated skin with plenty of water. Remove all contaminated clothing and footwear. Get medical attention if experiencing symptoms.
- Beads and Buffers Plate: Rinse contaminated skin with plenty of water. Remove all contaminated clothing and footwear. Rinse immediately contaminated clothing with plenty of water before removing clothes, or wear gloves. Continue rinsing for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean footwear thoroughly before reuse.
- Cardiovascular Probes Strip: No known significant effects or critical hazards.
- Elution buffer: Rinse immediately contaminated clothing and skin with plenty of water and remove all contaminated clothes and footwear. Get medical attention if symptoms persist.
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- **If swallowed:**
 - Fragmentation Buffer: Rinse mouth with water. Remove dentures, if present. If the material has been swallowed and the exposed person is conscious, give small amounts 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. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
 - Fragmentation Enzyme: Rinse mouth with water. Remove dentures, if present. If the material has been swallowed and the exposed person is conscious, give small amounts 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. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
 - Reagents Plate: Rinse mouth with water. If the material has been swallowed and the exposed person is conscious, give small amounts of water to drink. Do not induce

vomiting unless directed to do so by medical personnel. Get medical attention if experiencing symptoms.

- Index Strip: Rinse mouth with water. If the material has been swallowed and the exposed person is conscious, give small amounts of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if experiencing symptoms.
- Beads and Buffers Plate Remove dentures, if present and feasible to remove. If the material has been swallowed and the exposed person is conscious, give small amounts 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 if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Ensure sufficient supply of air. Loosen tight clothing such as a collar, tie, belt or waistband.
- Cardiovascular Probes Strip: No known significant effects or critical hazards.
- If accidentally swallowed, immediately call a doctor/physician. Rinse mouth with water. Never give anything by mouth to an unconscious person.

▪ **Most important symptoms/effects, acute and/or delayed:**

- Fragmentation Buffer: No known significant adverse effects.
- Fragmentation Enzyme: Causes eye irritation
- Reagent Plate: No known significant effects or critical hazards.
- Index Strip: No known significant effects or critical hazards.
- Beads and Buffers Plate:
 - Causes severe eye irritation.
 - Causes skin irritation. May cause an allergic skin reaction.
- Cardiovascular Probes Strip: No known significant effects or critical hazards.
- Elution Buffer: No known significant effects or critical hazards.

▪ **Over-exposure signs/symptoms:**

- Fragmentation Buffer: Adverse symptoms may include the following:
 - Low foetal weight.
 - Increased foetal lethality.
 - Skeletal malformations.
- Fragmentation Enzyme: Adverse symptoms may include the following:
 - Irritation.
 - Watering eyes.

- Reddening.
 - Reagent Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.
 - Beads and Buffers Plate:
 - Eye contact: pain or irritation. Watering eyes. Reddening.
 - Skin contact: irritation. Reddening.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.
 - Elution Buffer: No known significant effects or critical hazards.
- **Indication of any immediate medical attention and special treatment needed:**
 - Fragmentation Buffer: Symptomatic treatment. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled. No action should be taken involving any personal risk to the person providing aid. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.
 - Fragmentation Enzyme: Symptomatic treatment. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled. No action should be taken involving any personal risk to the person providing aid. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.
 - Reagent Plate: Symptomatic treatment. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
 - Index Strip: Symptomatic treatment. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
 - Beads and Buffers Plate: In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Symptomatic treatment. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
 - Cardiovascular Probes Strips: No available information.
 - Elution Buffer: No available information.

5. Firefighting measures

- **Extinguishing media**
 - Fragmentation Buffer: Use an extinguishing agent suitable for the surrounding fire.
 - Fragmentation Enzyme: Use an extinguishing agent suitable for the surrounding fire.
 - Reagent Plate: Use an extinguishing agent suitable for the surrounding fire.
 - Index Strip: Use an extinguishing agent suitable for the surrounding fire.
 - Beads and Buffers Plate: Use an extinguishing agent suitable for the surrounding fire.
 - Cardiovascular Probes Strip: Use an extinguishing agent suitable for the surrounding

- fire.
- Elution Buffer: Use an extinguishing agent suitable for the surrounding fire.
- **Special hazards arising from the substance or mixture:**
 - Fragmentation Buffer: Pressure may increase and contained may explode if heated or in case of fire.
 - Fragmentation Enzyme: Pressure may increase and contained may explode if heated or in case of fire.
 - Reagent Plate: Pressure may increase and contained may explode if heated or in case of fire.
 - Index Strip: Pressure may increase and contained may explode if heated or in case of fire.
 - Beads and Buffers Plate: Highly flammable liquid and vapour. Liquid waste leakage to the sewage system may pose a fire/explosion hazard. Pressure may increase and contained may explode if heated or in case of fire. This material is toxic to aquatic life with long-lasting effects. Firefighting water contaminated with this material must be prevented from entering waterways, drains, or sewage systems.
 - Cardiovascular Probes Strips: No available information.
 - Elution Buffer: Exposure to decomposition products may be harmful to human health.
- **Hazardous thermal decomposition products:**
 - Fragmentation Buffer: Decomposition products may include the following materials: halogenated compounds and metallic oxides.
 - Fragmentation Enzyme: Decomposition products may include the following materials: carbon dioxide and carbon monoxide.
 - Reagent Plate: Decomposition products may include the following materials: carbon dioxide, carbon monoxide, halogenated compounds and metallic oxides.
 - Index Plate: No available information.
 - Beads and Buffers Plate: Decomposition products may include the following materials: carbon dioxide, carbon monoxide, halogenated compounds and metallic oxides.
 - Cardiovascular Probes Strips: No available information.
 - Elution Buffer: No available information.
- **Protective actions and protective equipment for fire-fighters:**
 - Fragmentation Buffer: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No additional action shall be taken involving any personal risk or without suitable training.
 - Fragmentation Enzyme: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No additional action shall be taken involving any personal risk or without suitable training.

- Reagent Plate: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No additional action shall be taken involving any personal risk or without suitable training. Fire-fighters should wear appropriate protective equipment with a full face-piece operated in positive pressure mode Firefighting equipment (including protective helmets, gloves, and boots) compliant with the European EN 469:2020 standard provide the minimum protection level in the event of a chemical incident.
- Index Strip: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No additional action shall be taken involving any personal risk or without suitable training. Fire-fighters should wear appropriate protective equipment with a full face-piece operated in positive pressure mode Firefighting equipment (including protective helmets, gloves, and boots) compliant with the European EN 469:2020 standard provide the minimum protection level in the event of a chemical incident.
- Beads and Buffers Plate: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No additional action shall be taken involving any personal risk or without suitable training. Move containers away from fire if this can be done without risk. Use water spray to keep fire-exposed containers cool.
- Cardiovascular Probes Strip: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No additional action shall be taken involving any personal risk or without suitable training. Move containers away from fire if this can be done without risk. Use water spray to keep fire-exposed containers cool.
- Elution Buffer: No available information.

6. Accidental release measures

- **Personal precautions, protective equipment and emergency procedures:**
 - For non-emergency personnel:
 - Fragmentation Buffer: 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 spilled material. Wear appropriate personal protective equipment.
 - Fragmentation Enzyme: No additional 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 spilled material. Wear appropriate personal protective equipment.
 - Reagent Plate: No additional 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

spilled material. Wear appropriate personal protective equipment.

- Index Plate: No additional 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 spilled material. Wear appropriate personal protective equipment.
 - Beads and Buffers Plate: Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. In clinical information sources No flares, smoking or flames in hazard area. Avoid breathing mist/vapours. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Wear appropriate personal protective equipment.
 - Cardiovascular Probes Strips: No available information.
 - Elution Buffer: No available information.
- o For emergency responders:
 - Fragmentation Buffer: If specialized 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".
 - Fragmentation Enzyme: If specialized 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".
 - Reagent Plate: If specialized 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".
 - Index Strip: If specialized 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".
 - Beads and Buffers Plate: If specialized 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".
 - Cardiovascular Probes Strip: If specialized 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".
 - Elution Buffer: No available information.
- **Environmental precautions:**
 - o Fragmentation Buffer: Avoid dispersal of spilled 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).

- Fragmentation Enzyme: Avoid dispersal of spilled 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).
- Reagent Plate: Avoid dispersal of spilled 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).
- Index Strip: Avoid dispersal of spilled 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).
- Beads and Buffers Plate: Avoid dispersal of spilled 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 pollutant material. Can be hazardous to the environment if large amounts are released. Collect spillage.
- Cardiovascular Probes Strip: Avoid dispersal of spilled 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).
- Elution Buffer: No available information.

▪ **Methods and material for containment and cleaning up:**

- Fragmentation Buffer: If possible, stop the flow of the material. Move containers from spill area. If water-soluble, flush with water and mop. Alternatively, or if not water-soluble, soak up with an inert dry material and place in an appropriate waste container for disposal. Dispose of via a licensed waste disposal contractor.
- Fragmentation Enzyme: If possible, stop the flow of the material. Move containers from spill area. If water-soluble, flush with water and mop. Alternatively, or if not water-soluble, soak up with an inert dry material and place in an appropriate waste container for disposal. Dispose of via a licensed waste disposal contractor.
- Reagent Plate: If possible, stop the flow of the material. Move containers from spill area. If water-soluble, flush with water and mop. Alternatively, or if not water-soluble, soak up with an inert dry material and place in an appropriate waste container for disposal. Dispose of via a licensed waste disposal contractor.
- Index Strip: If possible, stop the flow of the material. Move containers from spill area. If water-soluble, flush with water and mop. Alternatively, or if not water-soluble, soak up with an inert dry material and place in an appropriate waste container for disposal. Dispose of via a licensed waste disposal contractor.
- Beads and Buffers Plate: If possible, stop the flow of the material. Move containers from spill area. If water-soluble, flush with water and mop. Alternatively, or if not

water-soluble, soak up with an inert dry material and place in an appropriate waste container for disposal. Dispose of via a licensed waste disposal contractor.

- Cardiovascular Probes Strip: If possible, stop the flow of the material. Move containers from spill area. If water-soluble, flush with water and mop. Alternatively, or if not water-soluble, soak up with an inert dry material and place in an appropriate waste container for disposal. Dispose of via a licensed waste disposal contractor.
- Elution Buffer: No available information.

7. Handling and storage

■ Precautions for safe handling

- Fragmentation Buffer: Use personal protective equipment as required (see Section 8).
- Fragmentation Enzyme: Use personal protective equipment as required (see Section 8). Reagent Plate: Use personal protective equipment as required (see Section 8).
- Index Strip: Use personal protective equipment as required (see Section 8).
- Beads and Buffers Plate: Use personal protective equipment as required (see Section 8).
- Cardiovascular Probes Strip: Use personal protective equipment as required (see Section 8).
- Elution Buffer: Use personal protective equipment as required (see Section 8).

■ Conditions for safe storage, including any incompatibilities

- Fragmentation Buffer: 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 drinks. 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 unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.
- Fragmentation Enzyme: 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 drinks. 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 unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.
- Reagent Plate: 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 drinks. 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 unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

- Index Strip: 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 drinks. 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 unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.
- Beads and Buffers Plate: 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 drinks. 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 unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.
- Cardiovascular Probes Strip: 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 drinks. 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 unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.
- Elution Buffer: 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 drinks. 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 unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

- **Specific end use(s)**

The product and all its components are for *in vitro* diagnostic use only.

8. Exposure control/personal protection

Control parameters:

- **Occupational exposure limits**

- Fragmentation Buffer: Unknown.
- Fragmentation Enzyme: See table below.
- Reagents Plate: If this product contains ingredients with exposure limits, personal, workplace or biological supervision to determine the efficacy of ventilation or other control measures and/or the need for respiratory protection. Monitoring standards must be used as a reference, such as the following: European standard EN 689 (Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values) 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 exposure. Procedures for the determination of the concentration of chemical agents – Basic performance requirements). National guidelines pertaining to methods for the determination of hazardous substances must also be used as a reference.
- Index Strip: Monitoring standards must be used as a reference, such as the following: European standard EN 689 (Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values) 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 exposure. Procedures for the determination of the concentration of chemical agents – Basic performance requirements). National guidelines pertaining to methods for the determination of hazardous substances must also be used as a reference.
- Beads and Buffers Plate: Monitoring standards must be used as a reference, such as the following: European standard EN 689 (Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values) 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 exposure. Procedures for the determination of the concentration of chemical agents – Basic performance requirements). National guidelines pertaining to methods for the determination of hazardous substances must also be used as a reference.
- Elution Buffer: Monitoring standards must be used as a reference, such as the following: European standard EN 689 (Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values) 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 exposure. Procedures for the determination of the concentration of chemical agents - Basic performance requirements). National guidelines pertaining to methods for the determination of hazardous substances must also be used as a reference.

- Cardiovascular Probes Strips: No available information.

Exposure controls:

Component/Ingredient	Exposure limits
Fragmentation Enzyme	
Glycerol	INSHT (Spain, 4/2021) VLA-ED: 10 mg/m ³ 8 h. Form: mist.

	OSHA PEL 1989 (United States, 3/1989) TWA: 5 mg/m ³ 8 h. Form: respirable fraction TWA: 10 mg/m ³ 8 h. Form: total dust TWA: 5 mg/m ³ 8 h. Form: respirable fraction TWA: 15 mg/m ³ 8 h. Form: total dust
Reagent Plate	
Glycerol	INSHT (Spain, 2/2019) VLA-ED: 10 mg/m ³ 8 h Form: mist.
Beads and Buffers Plate	
Ethanol	INSHT (Spain, 4/2021) VLA-EC: 1000 ppm 15 minutes. VLA-EC: 1910 mg/m ³ 15 minutes

Component/Ingredient	Type	Exposure	Value	Population	Effects
Fragmentation Buffer					
Cesium chloride					
	DNEL	Long-term inhalative	1.47 mg/m ³	Workers	Systemic
	DNEL	Long-term dermal	4.18 mg/kg bw/day	Workers	Systemic
Beads and Buffers					
Plate	DNEL	Long-term inhalative	0.02 mg/m ³	General population	Local
Reaction mass of 5-	DNEL	Long-term inhalative	0.02 mg/m ³	Workers	Local
chloro-2-methyl-2H-	DNEL	Long-term inhalative	0.04 mg/m ³	General population	Local
isothiazol-3-one and	DNEL	Short-term inhalative	0.04 mg/m ³	Workers	Local
2-methyl-2H-	DNEL	Long-term Oral	0.09 mg/kg	General population	Systemic
isothiazol-3-one (3:1)	DNEL	Short-term Oral	bw/day	General population	Systemic
	DNEL	Short-term Oral	0.11 mg/kg		
	DNEL		bw/day		
Ethanol	DNEL	Long-term oral	87 mg/kg	General population	Systemic
	DNEL	Long-term inhalative	bw/day	General population	Systemic
	DNEL	Long-term Dermal	114 mg/m ³	General population	Systemic
	DNEL	Long-term dermal	206 mg/kg	Workers	Systemic
	DNEL	Short-term inhalative	bw/day	General population	Local
	DNEL	Long-term inhalative	343 mg/kg	Workers	Systemic
	DNEL	Short-term inhalative	bw/day	Workers	Local
			950 mg/m ³		
			950 mg/m ³		
			1900 mg/m ³		

- **Personal protective equipment**

- **RESPIRATORY PROTECTION:**

- Fragmentation Buffer: Based on the assessed hazard and exposure, select a respirator that meets the appropriate standards or certifications. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
- Fragmentation Enzyme: Based on the assessed hazard and exposure, select a respirator

that meets the appropriate standards or certifications. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

- Reagent Plate: Based on the assessed hazard and exposure, select a respirator that meets the appropriate standards or certifications. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
- Index Strip: Based on the assessed hazard and exposure, select a respirator that meets the appropriate standards or certifications. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
- Beads and Buffers Plate: Based on the assessed hazard and exposure, select a respirator that meets the appropriate standards or certifications. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
- Elution Buffer: Based on the assessed hazard and exposure, select a respirator that meets the appropriate standards or certifications. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
- Cardiovascular Probes Strips: No available information.

- HAND PROTECTION:
 - Fragmentation Buffer: Chemical-resistant, impervious gloves complying with an approved standard must 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.
 - Fragmentation Enzyme: Chemical-resistant, impervious gloves complying with an approved standard must 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.
 - Reagent Plate: 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.
- Index Strip: 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.
 - Beads and Buffer Plate: 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.
 - Cardiovascular Probes Strip: 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.
 - Elution Buffer: 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.
- EYE PROTECTION:
- Fragmentation Buffer: 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: chemical splash safety goggles.
 - Fragmentation Buffer: 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: chemical splash safety goggles.
 - Reagent Plate: 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 goggles with side shields.

- Index Strip: 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 goggles with side shields.
- Beads and Buffers Plate: 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 goggles with side shields.
- Elution Buffer: No available information.
- Cardiovascular Probes Strips: No available information.
- BODY AND SKIN PROTECTION:
 - Fragmentation Buffer: Chemical-resistant, impervious gloves complying with an approved standard must 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.
 - Fragmentation Enzyme: Chemical-resistant, impervious gloves complying with an approved standard must 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.
 - Reagent Plate: Personal protective equipment for the body must be selected based on the task being performed and the risks involved and must be approved by a specialist before handling this product.
 - Index Strip: Personal protective equipment for the body must be selected based on the task being performed and the risks involved and must be approved by a specialist before handling this product.
 - Beads and Buffers Plate: Personal protective equipment for the body must be selected

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

- Cardiovascular Probes Strip: Personal protective equipment for the body must be selected based on the task being performed and the risks involved and must be approved by a specialist before handling this product.
 - Elution Buffer: Body protection measures must be selected based on the amount and concentration of the hazardous substance present in the workplace. Chemical protective footwear.
- **Environmental exposure controls:**
- Fragmentation Buffer: Emissions from ventilation or work process equipment should be checked to ensure that they comply with the requirements of the applicable 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.
 - Fragmentation Enzyme: Emissions from ventilation or work process equipment should be checked to ensure that they comply with the requirements of the applicable 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.
 - Reagent Plate: Emissions from ventilation or work process equipment should be checked to ensure that they comply with the requirements of the applicable 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.
 - Index Strip: Emissions from ventilation or work process equipment should be checked to ensure that they comply with the requirements of the applicable 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.
 - Beads and Buffers Plate: Emissions from ventilation or work process equipment should be checked to ensure that they comply with the requirements of the applicable 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.
 - Elution Buffer: No available information.
 - Cardiovascular Probes Strips: No available information.

9. Physical and chemical properties

- **Appearance:**
 - Fragmentation Buffer: Liquid
 - Fragmentation Enzyme: Liquid
 - Reagent Plate: Liquid
 - Beads and Buffers Plate: Liquid
 - Index strip: Liquid
 - Elution Buffer: Liquid
 - Cardiovascular Probes Strip: Liquid

- **Color:**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: Not available.

- **Odor:**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: Not available.

- **Odor threshold:**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available. Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: Not available.

- **pH:**
 - Fragmentation Buffer: 7.5

- Fragmentation Enzyme: 7.5
- Reagent Plate: Not available.
- Index strip: 7.5
- Beads and Buffers Plate: 7-7.5
- Index Strip: Not available.
- Elution Buffer: 8.5
- Cardiovascular Probes Strip: Not available.

▪ **Molecular weight:**

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available. Reagent Plate: Not available.
- Beads and Buffers Plate: Not available.
- Index Strip: Not available.
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

▪ **Melting point/freezing point:**

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available.
- Beads and Buffers Plate: 0 °C
- Reagent Plate: 0 °C
- Index Strip: 0 °C
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

▪ **Boiling point/boiling range:**

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available.
- Reagent Plate: Not available.
- Beads and Buffers Plate: 100 °C
- Reagent Plate: Not available.
- Index Strip: 100 °C
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

▪ **Flash point:**

Reagent/Component	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method

Fragmentation Buffer						
(R*, R*)-1,4-dimercaptobutane-2,3-diol	>110	>230				
Fragmentation Enzyme						
Glycerol			Pensky-Marlens	177	350.6	
Reagent Plate						
Edetic acid	>100	>212	DIN51758	-	-	-
(R*, R*)-1,4-dimercaptobutane-2,3-diol	>110	230	DIN51758	-	-	-
Beads and Buffers Plate						
Ethanol	-18 to 23	-	-	-	-	-
Polyethylene glycol	171 to 235	-	-	199 to 238	-	-

▪ **Autoignition temperature:**

Reagent/Component	°C	°F
Fragmentation Buffer		
Cesium chloride	>400	>752
Fragmentation Enzyme		
Glycerol	370	698

▪ **Evaporation rate:**

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available.
- Reagent Plate: Not available.
- Beads and Buffers Plate: Not available.
- Index Strip: Not available.
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

▪ **Flammability:**

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available.
- Reagent Plate: Not available.
- Beads and Buffers Plate: Not available.
- Index Strip: Not available.
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

▪ **Upper and lower explosion limit:**

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available.
- Reagent Plate: Not available.
- Beads and Buffers Plate: Not available.
- Index Strip: Not available.
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

▪ Vapor pressure:

Reagent/Component	Vapor pressure at 20 °C			Vapor pressure at 50 °C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Fragmentation Buffer						
Water	23.8	3.2	-	92.258	12.3	-
2-Amino-2(hydroxymethyl)propane-1,3-diol hydrochloride	0.000027	0.0000036	-	0.000007501	0.000001	-
Fragmentation Enzyme						
Water	23.8	3.2	-	92.258	12.3	-
Glycerol	0	0	-	0	0	-
Reagent Plate						
Water	23.8	3.2	-	-	-	-
Sulfuric acid, magnesium salt, hydrate (1:1:7)	<0.1	<0.013	-	-	-	-
Beads and Buffers Plate						
Water	23.8	3.2	-	92.258	12.3	-
2-Amino-2(hydroxymethyl)propane-1,3-diol hydrochloride	0.000027	0.0000036	-	0.000007501	0.000001	-
Ethanol	42.95	5.7	-	-	-	-
Index Plate						
Water	23.8	3.2	-	92.258	12.3	-

▪ Vapor density:

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available.
- Reagent Plate: Not available.
- Beads and Buffers Plate: Not available.
- Index Strip: Not available.
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

- **Relative density:**

 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: 1 g/cm³
 - Cardiovascular Probes Strip: Not available.

- **Solubility:**

 - Fragmentation Buffer: Easily soluble in cold water and in hot water.
 - Fragmentation Enzyme: Easily soluble in cold water and in hot water.
 - Reagent Plate: Soluble in water.
 - Beads and Buffers Plate: Soluble in water.
 - Index Strip: Soluble in water.
 - Elution Buffer: Soluble in water.
 - Cardiovascular Probes Strip: No data available.

- **Partition coefficient n-octanol/water:**

 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: No data available.

- **Viscosity:**

 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: No data available.

▪ **Explosive properties:**

Reagent/Component	°C	°F	Method
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Fragmentation Buffer			
Caesium chloride	>400	>752	-
Fragmentation Buffer			
Glycerol	370	698	-
Reagent Plate			
Polyethylene glycol	360	680	-
Glycerol			
Glycerol	370	698	-

- **Oxidizing properties:**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: Not available.

- **Decomposition temperature:**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: Not available.

10. Stability and reactivity

- **Reactivity:**

No specific test data related to reactivity available for this product or its ingredients.

- **Chemical stability:**

The product and its components are stable under normal conditions of use.

- **Possibility of hazardous reactions:**

Under normal conditions of storage and use, no hazardous reactions will occur in the product or its

ingredients.

▪ **Conditions to avoid:**

No specific data available.

▪ **Incompatible materials:**

- Fragmentation Buffer: May react or be incompatible with oxidizing materials.
- Fragmentation Enzyme: May react or be incompatible with oxidizing materials.
- Reagent Plate: May react or be incompatible with oxidizing materials.
- Beads and Buffers Plate: May react or be incompatible with oxidizing materials.
- Index Strip: May react or be incompatible with oxidizing materials.
- Elution Buffer: No available information.
- Cardiovascular Probes Strip: No available information.

▪ **Hazardous decomposition products:**

Under normal conditions of storage and use, no hazardous reactions should not be produced from the product and/or its ingredients.

11. Toxicological information

➤ **Information on toxicological effects:**

▪ **Acute toxicity:**

- Reagent Plate: Not available.
- Index Strip: Not available.
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

Reagent/Component	Result	Species	Dose	Exposure
Fragmentation Buffer				
Caesium chloride	Oral LD50	Rat	2004 mg/kg	-
Fragmentation Enzyme				
Glycerol	Oral LD50	Rat	12600 mg/kg	-
Beads and Buffers Plate				
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-	Vapor inhalation LC50	Rat	0.33 mg/l	4 hours

one (3:1)	Dermal LD50	Rabbit	87.12 mg/kg	-
	Oral LD50	Rat	53 mg/kg	-
Ethanol	Vapor inhalation	Rat	124700 mg/m ³	4 hours
	LC50	Rat	7 g/kg	-
	Oral LD50			

▪ Acute toxicity estimates:

Reagent/Component	Oral (mg/kg)	Dermal (mg/kg)	Gas inhalation (ppm)	Vapor inhalation (mg/l)	Dust and mist inhalation (mg/l)
Fragmentation Buffer	119030.6	N/A	N/A	N/A	N/A
Caesium chloride	2004	N/A	N/A	N/A	N/A
Fragmentation Enzyme					
Glycerol	12600	N/A	N/A	N/A	N/A
Beads and Buffers					
Plate					
Beads	29444.4	48400	N/A	162.3	N/A
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	53	87.12	N/A	0.5	N/A
Ethanol	7000	N/A	N/A	124.7	N/A

▪ Irritation/Corrosion:

- Reagent Plate: Not available.
- Reagent Plate: Not available.
- Index Strip: Not available.
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

Reagent/Component	Result	Species	Score	Exposure	Observations
Fragmentation					
Enzyme					
Glycerol	Eyes-moderately irritant	Rabbit	-	24 hours 500 mg	-
	Skin-moderately irritant	Rabbit	-	24 hours 500 mg	-
<hr/>					
Beads and Buffers Plate					
Ethanol	Eyes-mildly irritant	Rabbit	-	24 hours 500 mg	-
	Eyes-moderately irritant	Rabbit	-	0.0666667 minutes 100 mg	-
	Eyes-moderately irritant	Rabbit	-	100 µl	-

- **Respiratory sensitisation:**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: Not available.

- **Specific target organ toxicity (single exposure):**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.
 - Elution Buffer: No known significant effects or critical hazards.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Specific target organ toxicity (repeat exposure):**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.

- Index Strip: No known significant effects or critical hazards.
- Elution Buffer: No known significant effects or critical hazards.
- Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Carcinogenicity:**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.
 - Elution Buffer: No known significant effects or critical hazards.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Germ cell mutagenicity:**
 - Fragmentation Buffer: No known significant effects or critical hazards.
 - Fragmentation Enzyme: No known significant effects or critical hazards.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.
 - Elution Buffer: No known significant effects or critical hazards.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Reproductive toxicity:**
 - Fragmentation Buffer: Suspected of damaging fertility or the unborn child.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.
 - Elution Buffer: No known significant effects or critical hazards.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Aspiration hazard:**
 - Fragmentation Buffer: Symptoms may include low foetal weight, increased foetal lethality, skeletal malformations.
 - Fragmentation Enzyme: No known significant effects or critical hazards.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.

- Elution Buffer: No known significant effects or critical hazards.
- Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Potential acute health effects:**
 - Fragmentation Buffer: No known significant effects or critical hazards.
 - Fragmentation Enzyme: May cause eye irritation
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.
 - Elution Buffer: No known significant effects or critical hazards.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Symptoms related to physical, chemical and toxicological characteristics:**
 - Fragmentation Buffer: Symptoms may include low foetal weight, increased foetal lethality, skeletal malformations.
 - Fragmentation Enzyme: No known significant effects or critical hazards.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.
 - Elution Buffer: No known significant effects or critical hazards.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Delayed and immediate effects as well as chronic effects from short- and long-term exposure:**
 - Short-term exposure:
 - Fragmentation Buffer: No known significant effects or critical hazards.
 - Fragmentation Enzyme: No known significant effects or critical hazards.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.
 - Elution Buffer: No known significant effects or critical hazards.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.

 - Long-term exposure:
 - Fragmentation Buffer: No known significant effects or critical hazards.
 - Fragmentation Enzyme: No known significant effects or critical hazards.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.

- Index Strip: No known significant effects or critical hazards.
- Elution Buffer: No known significant effects or critical hazards.
- Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Mutagenicity:**
 - Fragmentation Buffer: No known significant effects or critical hazards.
 - Fragmentation Enzyme: No known significant effects or critical hazards.
 - Reagent Plate: No known significant effects or critical hazards.
 - Beads and Buffers Plate: No known significant effects or critical hazards.
 - Index Strip: No known significant effects or critical hazards.
 - Elution Buffer: No known significant effects or critical hazards.
 - Cardiovascular Probes Strip: No known significant effects or critical hazards.

- **Other data:** N/A

- **Numerical measurements of toxicity:**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: Not available.

12. Ecological information

- **Ecotoxicity:**
 - Fragmentation Buffer: Not available.
 - Fragmentation Enzyme: Not available.
 - Reagent Plate: Not available.
 - Beads and Buffers Plate: Not available.
 - Index Strip: Not available.
 - Elution Buffer: Not available.
 - Cardiovascular Probes Strip: Not available.

Reagent/Component	Result	Species	Exposure time
Fragmentation Buffer			
Cesium chloride	Acute EC50/ 135000 µl/L Freshwater	Crustaceans – <i>Eudiaptomus padanus</i> ssp. <i>Padanus</i> – Adult	48 hours
	Acute LC50/ 7400 µl/L Freshwater	Daphnia – <i>Daphnia hialina</i> – Adult	48 hours
Beads and Buffers			
Plate			
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	Acute LC50 0.16 mg/l Freshwater	Daphnia	48 hours
	Acute LC50 0.19 mg/l Freshwater	Fish	96 hours
Ethanol	Chronic NOEC > 0.0464 mg/l Freshwater	Fish	96 hours
	Acute EC50 3306 mg/l Seawater	Seaweed- <i>Ulva pertusa</i>	96 hours
	Acute EC50 1074 mg/l Freshwater	Crustaceans- <i>Cypris subglobosa</i>	48 hours
	Acute LC50 5680 mg/l Freshwater	Daphnia- <i>Daphnia magna</i> -Neonate	48 hours
	Acute CL50 11000000 µg/l Seawater	Fish- <i>Alburnus alburnus</i>	96 hours
	Chronic NOEC 4.995 mg/l Seawater	Seaweed- <i>Ulva pertusa</i>	96 hours
	Chronic NOEC 100 µl/L Freshwater	Daphnia- <i>Daphnia magna</i> -Neonate	21 days

▪ **Persistence and degradability:**

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available.
- Reagent Plate: Not available.
- Beads and Buffers Plate: Not available.
- Index Strip: Not available.
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

Reagent/Component	Test	Result	Dose	Inoculation time	Inoculum
Beads					
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	OECD 301B Ready Biodegradability CO ₂ Evolution Test	62%-Easy-28 days	-	-	-

▪ **Bioaccumulative potential:**

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available.
- Reagent Plate: Not available.
- Index Strip: Not available.
- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.

Reagent/Component	LogPow	BCF	Potential
Beads			
Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	0.326	-	Low
Ethanol	-0.35	0.5	Low

▪ **Mobility in soil:**

- Fragmentation Buffer: Not available.
- Fragmentation Enzyme: Not available.
- Reagent Plate: Not available.
- Beads and Buffers Plate: Not available.
- Index Strip: Not available.

- Elution Buffer: Not available.
- Cardiovascular Probes Strip: Not available.
- **Other adverse effects:** No adverse effects or critical hazards are known for this product and its ingredients.
- **Results of the PBT and vPvB assessment:** The remaining product components and/or ingredients have not been determined to contain persistent, bioaccumulative and toxic (PBT) and/or very persistent and very bioaccumulative (vPvB) substances.

13. Disposal considerations

- **Waste disposal methods:**
 - Reagent Plate: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, its solutions and any byproducts should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Surplus and non-recyclable products must be disposed of 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.
 - Beads and Buffers Plate: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, its solutions and any byproducts should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Surplus and non-recyclable products must be disposed of 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.
 - Index Strip: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, its solutions and any byproducts should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Surplus and non-recyclable products must be disposed of 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.
 - Elution Buffer: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, its solutions and any byproducts should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Surplus and non-recyclable products must be disposed of 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.
 - Cardiovascular Probes Strip: The generation of waste should be avoided or minimized

wherever possible. Disposal of this product, its solutions and any byproducts should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Surplus and non-recyclable products must be disposed of 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:**

Based on current knowledge, the provider does not consider this product or its ingredients to be hazardous according to EU Directive 2008/98/EC.

▪ **Packaging:**

- Elution Buffer: The generation of waste should be avoided or minimized wherever possible. Waste packaging must be recycled. Incineration or landfill should only be considered when recycling is not feasible.
- Fragmentation Buffer: The generation of waste should be avoided or minimized wherever possible. Waste packaging must be recycled. Incineration or landfill should only be considered when recycling is not feasible.
- Reagent Plate: The generation of waste should be avoided or minimized wherever possible. Waste packaging must be recycled. Incineration or landfill should only be considered when recycling is not feasible.
- Beads and Buffers Plate: The generation of waste should be avoided or minimized wherever possible. Waste packaging must be recycled. Incineration or landfill should only be considered when recycling is not feasible.
- Index Strip: N/A
- Elution buffer: N/A
- Cardiovascular Probes Strip: N/A

▪ **Special precautions:**

- Fragmentation Buffer: Residual product and its containers must be disposed as safely as possible. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
- Fragmentation Enzyme: Residual product and its containers must be disposed as safely as possible. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
- Reagent Plate: Residual product and its containers must be disposed as safely as possible. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

- Beads and Buffers Plate: Residual product and its containers must be disposed as safely as possible. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
- Index Strip: Residual product and its containers must be disposed as safely as possible. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
- Elution Buffer: Residual product and its containers must be disposed as safely as possible. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
- Cardiovascular Probes Strip: Residual product and its containers must be disposed as safely as possible. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

14. Transport information

Shipping conditions:

Reagent/Component	Shipping method	Shipping temperature
Beads and Buffers Plate	Freeze packs	4 °C
Elution Buffer	Freeze packs	4 °C
Fragmentation Buffer	Dry ice	-20 °C
Fragmentation Enzyme	Dry ice	-20 °C
Reagent Plate	Dry ice	-20 °C
Index Strip	Dry ice	-20 °C
Cardiovascular Probes Strip	Dry ice	-20 °C

International regulations:

- DOT/TDG/Mexico/IMDG/IATA: Product not regulated by transport regulations.
- UNRTDG: Product not regulated as dangerous goods.
- IATA-DGR: Product not regulated as dangerous goods.
- IMDG-Code: Product not regulated as dangerous goods.

- Class of dangerous goods for transport: N/A

Special precautions for users:

- Transport within user’s premises: always transport in closed, secure containers in upright position. Ensure that the persons transporting the product know what to do in the event of an accident or spillage.
- Transport in bulk according to MARPOL annex II and IBC code: N/A.

15. Regulatory information

Transport information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances:
 - HAZARD CRITERIA
 - BEADS → Category E2
 - ETHANOL → Category P5c
 - REACH: Candidate List of substances of very high concern for Authorisation (article 59)
 - Not applicable
 - Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer:
 - Not applicable
 - Regulation (EU) No. 2019/1021 on persistent organic pollutants (recast):
 - Not applicable.
 - Regulation (EU) No. 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals:

Reagent/Component	EC Number	EC Number	Restriction
Reagent Plate	231-984-1	7783-20-2	65

- REACH – Authorisation list (Annex XIV):
 - Not applicable

- **Chemical safety assessment**

This product and its components contain substances for which chemical safety assessment could still be necessary

16. Other information

Procedure used to derive the classification:

Reagent/Component	Classification	Justification
Beads and Buffers Plate		
Beads	Skin Irrit. 2, H315	Calculation method
	Eye Irrit. 2, H319	Calculation method
	Skin Sens.1, H317	Calculation method
	Aquatic Chronic 2, H411	Calculation method
Ethanol	Flam. Liq. 2, H225	Based on test data
	Eye Irrit. 2, H319	Calculation method

Full text of abbreviated H statements:

Abbreviated H statements:	Full text
Fragmentation Buffer	
H361f	Suspected of damaging fertility
H411	Toxic to aquatic life with long lasting effects
Beads and Buffers Plate	
BEADS:	
H301	Toxic if swallowed
H310	Fatal in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes severe eye irritation.
H330	Fatal if inhaled
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
EUH071	Corrosive to the respiratory tract
ETHANOL:	
H225	Highly flammable liquid and vapour
H319	Causes severe eye irritation

Full text for hazard categories [CLP/GHS]:

Classification	Hazard categorization
Beads and Buffers Plate	
BEADS:	
Acute Tox. 2	Acute toxicity – Category 2
Acute Tox. 3	Acute toxicity – Category 3
Aquatic Acute 1	Hazardous to the aquatic environment (acute) – Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment (chronic) – Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment (chronic) – Category 2
Eye Irrit. 2	Serious eye damage/eye irritation – Category 2
Skin Corr. 1C	Skin corrosion/irritation – Category 1C
Skin Irrit. 2	Skin corrosion/irritation – Category 2
Skin Sens. 1	Skin sensitisation – Category 1
Skin Sens. 1A	Skin sensitisation – Category 1A
ETHANOL:	
Eye Irrit. 2	Serious eye damage/eye irritation – Category 2
Flam. Liq. 2	Flammable liquid – Category 2

Classification and processes used to derive the classification of the mixture in accordance with Regulation (EC) 1272/2008 (CLP):

Abbreviations and acronyms:

- ACGIH = American Conference of Governmental Industrial Hygienists
- AICS = Australian Inventory of Chemical Substances
- AIHA = American Industrial Hygiene Association
- ATE = Acute Toxicity Estimate
- BFC = Bioconcentration Factor
- CEPA = Canadian Environmental Protection Act
- DSL/NDL = Canada Domestic/Non-Domestic Substances List
- DOT = U.S. Department of Transportation
- EINECS/ELINCS = European Inventory of Existing Commercial Chemical Substances / European List of Notified Chemical Substances
- ENCS = Japanese List of Existing and New Chemical Substances
- EPA = U.S. Environmental Protection Agency
- GHS = Globally Harmonized System
- HMIS = Hazardous Materials Information System
- IARC = International Agency for Research on Cancer
- IATA = International Air Transport Association
- IBC = International Bulk Chemical (Code)
- IECSC = China Inventory of Existing Chemical Substances
- IMDG = International Maritime Code for Dangerous Goods
- KECL = Korea Existing Chemicals List
- **Log Kow** = Logarithm of octanol/water partition coefficient
- MARPOL = International Convention for the Prevention of Marine Pollution from Ships, 1973, with 1978 Protocol ("Marpol" = Marine Pollution)
- N/A = Not Available
- NIOSH = National Institute for Occupational Safety and Health
- NTP = U.S. National Toxicology Program
- NZIoC = New Zealand Inventory of Chemicals
- OELs = Occupational Exposure Limits
- OSHA = U.S. Occupational Safety and Health Administration
- PICCS = Philippine Inventory of Chemicals and Chemical Substances
- STEL = Short-Term Exposure Limit
- TSCA = U.S. Toxic Substances Control Act, Section 8(b), Inventory
- TWA = Time-Weighted Average
- UN = United Nations
- UNRTDG = United Nations Recommendations on the Transport of Dangerous Goods

Note:

The information above has been acquired by diligent review and investigation, and the recommendations herein are based on prudent application of professional judgment. The information herein is not intended to be exhaustive and is to be used only as a guide. All materials and mixtures may represent unknown hazards and must be used with caution. The company does not control the actual methods, amounts and conditions of use and therefore shall not be held liable for any loss or damage resulting from the handling or contact with the hereby described product.

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History of versions:

Version	Date	Description of changes
07	SEP 2024	Expansion of the document to cover the 16 sections required by the regulations.
06	APR 2023	Revision of document content.
05	Nov 2022	Change of manufacturer's address to: Health in Code S.L., Calle de la Travesía s/n, 15E Base 5, Valencia, 46024, Spain New contact for the toxicological information service.
04	Sep 2022	Update of regulatory information.
03	JUN 2022	Content review
02	OCT 2021	Change of the manufacturer's identification: from imegen S.L. to Health in Code S.L. Updated regulatory information.
01	JAN 2019	N/A