

SAFETY DATA SHEET



Atellica® IM Hepatitis A IgM (aHAVM)

SDS no.:

10995444

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

1.1 Product identifier

Product name : Atellica® IM Hepatitis A IgM (aHAVM)
Product code : 10995444, 11207243

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

Identified uses	aHAVM Lite Reagent	Diagnostic agents.
	aHAVM Solid Phase Reagent	Diagnostic agents.
	aHAVM Ancillary Well Reagent	Diagnostic agents.
	aHAVM Ancillary Pack Reagent	Diagnostic agents.
	aHAVM Calibrator Hi	Diagnostic agents.
	aHAVM Calibrator Lo	Diagnostic agents.

Restrictions on use For professional users only.

Supplier : Siemens Healthcare Diagnostics Limited
 Park View,
 Watchmoor Park,
 Camberley,
 Surrey,
 GU15 3YL
 United Kingdom

Phone: +44 (0) 345 600 1955

e-mail address of person responsible for this SDS : dx.msds.healthcare@siemens-healthineers.com

1.4 Emergency telephone number

CHEMTREC: +44 20 3807 3798

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition	aHAVM Lite Reagent	Mixture
	aHAVM Solid Phase Reagent	Mixture
	aHAVM Ancillary Well Reagent	Mixture
	aHAVM Ancillary Pack Reagent	Mixture
	aHAVM Calibrator Hi	Mixture
	aHAVM Calibrator Lo	Mixture

Classification according to UK CLP/GHS

aHAVM Calibrator Hi

Skin Sens. 1, H317
 Aquatic Chronic 3, H412

aHAVM Calibrator Lo

Skin Sens. 1, H317
 Aquatic Chronic 3, H412

The product is classified as hazardous according to UK CLP Regulation SI 2019/720 as amended.

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

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

2.2 Label elements

SECTION 2: Hazards identification

Hazard pictograms

:



Signal word

:	aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No signal word. No signal word. No signal word. No signal word. Warning Warning
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Hazard statements

:	aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. H317 - May cause an allergic skin reaction. H412 - Harmful to aquatic life with long lasting effects. H317 - May cause an allergic skin reaction. H412 - Harmful to aquatic life with long lasting effects.
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Precautionary statements

Prevention

:	aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not applicable. Not applicable. Not applicable. Not applicable. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P273 - Avoid release to the environment. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P273 - Avoid release to the environment.
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Response

:	aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not applicable. Not applicable. Not applicable. Not applicable. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P362 + P364 - Take off contaminated clothing and wash it before reuse. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P362 + P364 - Take off contaminated clothing and wash it before reuse.
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Storage

:	aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
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SECTION 2: Hazards identification

Disposal	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not applicable. Not applicable. Not applicable. Not applicable. P501 - Dispose of contents and container in accordance with all local, regional, and national regulations. P501 - Dispose of contents and container in accordance with all local, regional, and national regulations.
Supplemental label elements	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not applicable. Not applicable. Not applicable. Not applicable. Not applicable. Not applicable.
2.3 Other hazards		
Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB. This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
Other hazards which do not result in classification	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	None known. None known. None known. None known. None known. None known.
Additional information	: Potentially biohazardous material. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.	

Atellica® IM Hepatitis A IgM (aHAVM)

SECTION 3: Composition/information on ingredients

3.1 Substances	: aHAVM Lite Reagent	Mixture
	aHAVM Solid Phase Reagent	Mixture
	aHAVM Ancillary Well Reagent	Mixture
	aHAVM Ancillary Pack Reagent	Mixture
	aHAVM Calibrator Hi	Mixture
	aHAVM Calibrator Lo	Mixture

Product/ingredient name	Identifiers	%	Classification	Type
aHAVM Calibrator Hi reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	CAS: 55965-84-9 Index: 613-167-00-5	<0.025	Acute Tox. 3, H301 Acute Tox. 2, H310 Acute Tox. 2, H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071	[1]
aHAVM Calibrator Lo reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	CAS: 55965-84-9 Index: 613-167-00-5	<0.025	Acute Tox. 3, H301 Acute Tox. 2, H310 Acute Tox. 2, H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071 See Section 16 for the full text of the H statements declared above.	[1]

Type

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

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

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact	: aHAVM Lite Reagent	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.
	aHAVM Solid Phase Reagent	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.
	aHAVM Ancillary Well Reagent	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.
	aHAVM Ancillary Pack Reagent	Immediately flush eyes with plenty of water, occasionally lifting the upper and

SECTION 4: First aid measures

lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs. Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

aHAVM Calibrator Hi

aHAVM Calibrator Lo

Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

Inhalation

: aHAVM Lite Reagent

Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. 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.

aHAVM Solid Phase Reagent

Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. 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.

aHAVM Ancillary Well Reagent

Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. 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.

aHAVM Ancillary Pack Reagent

Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. 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. 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. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

aHAVM Calibrator Hi

aHAVM Calibrator Lo

Remove victim to fresh air and keep at rest in a position comfortable for

SECTION 4: First aid measures

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. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Skin contact : aHAVM Lite Reagent

aHAVM Solid Phase Reagent

aHAVM Ancillary Well Reagent

aHAVM Ancillary Pack Reagent

aHAVM Calibrator Hi

aHAVM Calibrator Lo

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion : aHAVM Lite Reagent

aHAVM Solid Phase Reagent

aHAVM Ancillary Well Reagent

Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Wash out mouth with water. If material

SECTION 4: First aid measures

aHAVM Ancillary Pack Reagent

has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

aHAVM Calibrator Hi

Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

aHAVM Calibrator Lo

Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention 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. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Protection of first-aiders : aHAVM Lite Reagent

aHAVM Solid Phase Reagent

No action shall be taken involving any personal risk or without suitable training.

aHAVM Ancillary Well Reagent

No action shall be taken involving any personal risk or without suitable training.

aHAVM Ancillary Pack Reagent

No action shall be taken involving any personal risk or without suitable training.

aHAVM Calibrator Hi

No action shall be taken involving any personal risk or without suitable training.

No action shall be taken involving any personal risk or without suitable training.

It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before

SECTION 4: First aid measures

aHAVM Calibrator Lo

removing it, or wear gloves.
No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No specific data. No specific data. No specific data. No specific data. No specific data. No specific data.
Inhalation	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No specific data. No specific data. No specific data. No specific data. No specific data. No specific data.
Skin contact	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No specific data. No specific data. No specific data. No specific data. Adverse symptoms may include the following: irritation redness Adverse symptoms may include the following: irritation redness
Ingestion	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No specific data. No specific data. No specific data. No specific data. No specific data. No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	: aHAVM Lite Reagent	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.
	aHAVM Solid Phase Reagent	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.
	aHAVM Ancillary Well Reagent	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.
	aHAVM Ancillary Pack Reagent	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need

SECTION 4: First aid measures

to be kept under medical surveillance for 48 hours.

Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments

aHAVM Calibrator Hi

No specific treatment.

No specific treatment.

No specific treatment.

No specific treatment.

No specific treatment.

No specific treatment.

aHAVM Calibrator Lo

aHAVM Lite Reagent

Not available.

Not available.

Not available.

Not available.

Not available.

Not available.

aHAVM Solid Phase Reagent

aHAVM Ancillary Well Reagent

aHAVM Ancillary Pack Reagent

aHAVM Calibrator Hi

aHAVM Calibrator Lo

aHAVM Lite Reagent

aHAVM Solid Phase Reagent

aHAVM Ancillary Well Reagent

aHAVM Ancillary Pack Reagent

aHAVM Calibrator Hi

aHAVM Calibrator Lo

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous combustion products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds
metal oxide/oxides

5.3 Advice for firefighters

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

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

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SECTION 6: Accidental release measures

6.2 Environmental precautions : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

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

Large spill : Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapour or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

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

7.2 Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

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SECTION 8: Exposure controls/personal protection

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Product/ingredient name	Type	Exposure	Value	Population	Effects
aHAVM Calibrator Hi reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	DNEL	Long term Inhalation	0.02 mg/m ³	General population	Local
	DNEL	Long term Inhalation	0.02 mg/m ³	Workers	Local
	DNEL	Short term Inhalation	0.04 mg/m ³	General population	Local
	DNEL	Short term Inhalation	0.04 mg/m ³	Workers	Local
	DNEL	Long term Oral	0.09 mg/kg bw/day	General population	Systemic
	DNEL	Short term Oral	0.11 mg/kg bw/day	General population	Systemic
aHAVM Calibrator Lo reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	DNEL	Long term Inhalation	0.02 mg/m ³	General population	Local
	DNEL	Long term Inhalation	0.02 mg/m ³	Workers	Local
	DNEL	Short term Inhalation	0.04 mg/m ³	General population	Local
	DNEL	Short term Inhalation	0.04 mg/m ³	Workers	Local
	DNEL	Long term Oral	0.09 mg/kg bw/day	General population	Systemic
	DNEL	Short term Oral	0.11 mg/kg bw/day	General population	Systemic

PNECs

No PNECs available

8.2 Exposure controls

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

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

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

SECTION 8: Exposure controls/personal protection**Skin protection**

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties**Appearance**

Physical state	: aHAVM Lite Reagent	Liquid.
	aHAVM Solid Phase Reagent	Liquid.
	aHAVM Ancillary Well Reagent	Liquid.
	aHAVM Ancillary Pack Reagent	Liquid.
	aHAVM Calibrator Hi	Liquid.
	aHAVM Calibrator Lo	Liquid.
Colour	: aHAVM Lite Reagent	Colourless.
	aHAVM Solid Phase Reagent	Colourless.
	aHAVM Ancillary Well Reagent	Colourless.
	aHAVM Ancillary Pack Reagent	Colourless.
	aHAVM Calibrator Hi	Colourless to light yellow.
	aHAVM Calibrator Lo	Colourless to light yellow.
Odour	: aHAVM Lite Reagent	Odorless.
	aHAVM Solid Phase Reagent	Odorless.
	aHAVM Ancillary Well Reagent	Odorless.
	aHAVM Ancillary Pack Reagent	Odorless.
	aHAVM Calibrator Hi	Bland.
	aHAVM Calibrator Lo	Bland.
Odour threshold	: Not relevant/applicable due to nature of the product.	
Melting point/freezing point	: Not relevant/applicable due to nature of the product.	
Softening point	: Not relevant/applicable due to nature of the product.	
Sublimation temperature	: Not relevant/applicable due to nature of the product.	
Initial boiling point and boiling range	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.

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SECTION 9: Physical and chemical properties

Flammability (solid, gas)	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not relevant/applicable due to nature of the product. Not relevant/applicable due to nature of the product. Not relevant/applicable due to nature of the product. Not relevant/applicable due to nature of the product. Not relevant/applicable due to nature of the product. Not relevant/applicable due to nature of the product.
Upper/lower flammability or explosive limits	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
Flash point	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	[Product does not sustain combustion.] [Product does not sustain combustion.] [Product does not sustain combustion.] [Product does not sustain combustion.] [Product does not sustain combustion.] [Product does not sustain combustion.]

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
aHAVM Lite Reagent Sorbitan monolaurate, ethoxylated	275	527		>149	>300.2	
aHAVM Solid Phase Reagent Sorbitan monolaurate, ethoxylated	275	527		>149	>300.2	
aHAVM Ancillary Well Reagent Sorbitan monolaurate, ethoxylated	275	527		>149	>300.2	
aHAVM Ancillary Pack Reagent Sorbitan monolaurate, ethoxylated	275	527		>149	>300.2	
aHAVM Calibrator Hi triethyl orthoformate	35	95				
aHAVM Calibrator Lo triethyl orthoformate	35	95				

Auto-ignition temperature :

Ingredient name	°C	°F	Method
aHAVM Lite Reagent sodium azide	309	588.2	EU A.16
aHAVM Solid Phase Reagent sodium azide	309	588.2	EU A.16
aHAVM Ancillary Well Reagent sodium azide	309	588.2	EU A.16

Atellica® IM Hepatitis A IgM (aHAVM)

SECTION 9: Physical and chemical properties

aHAVM Ancillary Pack Reagent			
sodium azide	309	588.2	EU A.16
aHAVM Calibrator Hi			
1,1'-oxydipropan-2-ol	310	590	
aHAVM Calibrator Lo			
1,1'-oxydipropan-2-ol	310	590	

Decomposition temperature : Not relevant/applicable due to nature of the product.

pH : aHAVM Lite Reagent 7.95 to 8.05
aHAVM Solid Phase Reagent 7.95 to 8.05
aHAVM Ancillary Well Reagent 7.95 to 8.05
aHAVM Ancillary Pack Reagent 7.95 to 8.05
aHAVM Calibrator Hi Not applicable.
aHAVM Calibrator Lo Not applicable.

Viscosity : aHAVM Lite Reagent Not available.
aHAVM Solid Phase Reagent Not available.
aHAVM Ancillary Well Reagent Not available.
aHAVM Ancillary Pack Reagent Not available.
aHAVM Calibrator Hi Not available.
aHAVM Calibrator Lo Not available.

Solubility(ies) :
Not available.

Solubility in water : Not relevant/applicable due to nature of the product.

Miscible with water : Not relevant/applicable due to nature of the product.

Partition coefficient: n-octanol/ water : Not relevant/applicable due to nature of the product.

Vapour pressure :

Ingredient name	Vapour Pressure at 20°C			Vapour pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
aHAVM Lite Reagent						
water	23.8	3.2				
aHAVM Solid Phase Reagent						
water	23.8	3.2				
aHAVM Ancillary Well Reagent						
water	23.8	3.2				
aHAVM Ancillary Pack Reagent						
water	23.8	3.2				
aHAVM Calibrator Hi						
water	23.8	3.2				
aHAVM Calibrator Lo						
water	23.8	3.2				

Evaporation rate : Not relevant/applicable due to nature of the product.

SECTION 9: Physical and chemical properties

Relative density	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	1
	aHAVM Calibrator Lo	1
Density	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.
Vapour density	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.
Explosive properties	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.
Oxidising properties	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.
<u>Particle characteristics</u>		
Median particle size	: Not applicable.	
9.2 Other information		
Fire point	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.
Burning time	: Not relevant/applicable due to nature of the product.	
Fundamental burning velocity	: Not relevant/applicable due to nature of the product.	
Burning rate	: Not relevant/applicable due to nature of the product.	
SADT	: Not relevant/applicable due to nature of the product.	
SAPT	: Not relevant/applicable due to nature of the product.	
Heat of reaction	: Not relevant/applicable due to nature of the product.	
Heat of combustion	: Not relevant/applicable due to nature of the product.	
Flow time (ISO 2431)	: Not relevant/applicable due to nature of the product.	
Molecular weight	: Not relevant/applicable due to nature of the product.	

Atellica® IM Hepatitis A IgM (aHAVM)

SECTION 10: Stability and reactivity

- 10.1 Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- 10.2 Chemical stability** : The product is stable.
- 10.3 Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- 10.4 Conditions to avoid** : No specific data.
- 10.5 Incompatible materials** : No specific data.
- 10.6 Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
aHAVM Calibrator Hi reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	LD50 Oral	Rat	53 mg/kg	-
aHAVM Calibrator Lo reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	LD50 Oral	Rat	53 mg/kg	-

Conclusion/Summary : aHAVM Lite Reagent Not available.
aHAVM Solid Phase Reagent Not available.
aHAVM Ancillary Well Reagent Not available.
aHAVM Ancillary Pack Reagent Not available.
aHAVM Calibrator Hi Not available.
aHAVM Calibrator Lo Not available.

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
aHAVM Calibrator Hi reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	53	50	N/A	0.5	N/A
aHAVM Calibrator Lo reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	53	50	N/A	0.5	N/A

Irritation/Corrosion

Atellica® IM Hepatitis A IgM (aHAVM)

SECTION 11: Toxicological information

Product/ingredient name	Result	Species	Score	Exposure	Observation
aHAVM Calibrator Hi reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	Skin - Severe irritant	Human	-	0.01 %	-
aHAVM Calibrator Lo reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	Skin - Severe irritant	Human	-	0.01 %	-

Conclusion/Summary

Skin	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
Eyes	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
Respiratory	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.

Sensitisation

Conclusion/Summary

Skin	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
Respiratory	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.

Mutagenicity

Conclusion/Summary

: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
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Carcinogenicity

SECTION 11: Toxicological information

Conclusion/Summary	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
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Reproductive toxicity

Conclusion/Summary	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
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Teratogenicity

Conclusion/Summary	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
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Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
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Potential acute health effects

Eye contact	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
Inhalation	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.

SECTION 11: Toxicological information

Skin contact	: aHAVM Lite Reagent	No known significant effects or critical hazards.
	aHAVM Solid Phase Reagent	No known significant effects or critical hazards.
	aHAVM Ancillary Well Reagent	No known significant effects or critical hazards.
	aHAVM Ancillary Pack Reagent	No known significant effects or critical hazards.
	aHAVM Calibrator Hi aHAVM Calibrator Lo	May cause an allergic skin reaction. May cause an allergic skin reaction.
Ingestion	: aHAVM Lite Reagent	No known significant effects or critical hazards.
	aHAVM Solid Phase Reagent	No known significant effects or critical hazards.
	aHAVM Ancillary Well Reagent	No known significant effects or critical hazards.
	aHAVM Ancillary Pack Reagent	No known significant effects or critical hazards.
	aHAVM Calibrator Hi	No known significant effects or critical hazards.
	aHAVM Calibrator Lo	No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: aHAVM Lite Reagent	No specific data.
	aHAVM Solid Phase Reagent	No specific data.
	aHAVM Ancillary Well Reagent	No specific data.
	aHAVM Ancillary Pack Reagent	No specific data.
	aHAVM Calibrator Hi	No specific data.
	aHAVM Calibrator Lo	No specific data.
Inhalation	: aHAVM Lite Reagent	No specific data.
	aHAVM Solid Phase Reagent	No specific data.
	aHAVM Ancillary Well Reagent	No specific data.
	aHAVM Ancillary Pack Reagent	No specific data.
	aHAVM Calibrator Hi	No specific data.
	aHAVM Calibrator Lo	No specific data.
Skin contact	: aHAVM Lite Reagent	No specific data.
	aHAVM Solid Phase Reagent	No specific data.
	aHAVM Ancillary Well Reagent	No specific data.
	aHAVM Ancillary Pack Reagent	No specific data.
	aHAVM Calibrator Hi	Adverse symptoms may include the following: irritation redness
	aHAVM Calibrator Lo	Adverse symptoms may include the following: irritation redness
Ingestion	: aHAVM Lite Reagent	No specific data.
	aHAVM Solid Phase Reagent	No specific data.
	aHAVM Ancillary Well Reagent	No specific data.
	aHAVM Ancillary Pack Reagent	No specific data.
	aHAVM Calibrator Hi	No specific data.
	aHAVM Calibrator Lo	No specific data.

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

Short term exposure

SECTION 11: Toxicological information

Potential immediate effects : aHAVM Lite Reagent Not available.
aHAVM Solid Phase Reagent Not available.
aHAVM Ancillary Well Reagent Not available.
aHAVM Ancillary Pack Reagent Not available.
aHAVM Calibrator Hi Not available.
aHAVM Calibrator Lo Not available.

Potential delayed effects : aHAVM Lite Reagent Not available.
aHAVM Solid Phase Reagent Not available.
aHAVM Ancillary Well Reagent Not available.
aHAVM Ancillary Pack Reagent Not available.
aHAVM Calibrator Hi Not available.
aHAVM Calibrator Lo Not available.

Long term exposure

Potential immediate effects : aHAVM Lite Reagent Not available.
aHAVM Solid Phase Reagent Not available.
aHAVM Ancillary Well Reagent Not available.
aHAVM Ancillary Pack Reagent Not available.
aHAVM Calibrator Hi Not available.
aHAVM Calibrator Lo Not available.

Potential delayed effects : aHAVM Lite Reagent Not available.
aHAVM Solid Phase Reagent Not available.
aHAVM Ancillary Well Reagent Not available.
aHAVM Ancillary Pack Reagent Not available.
aHAVM Calibrator Hi Not available.
aHAVM Calibrator Lo Not available.

Potential chronic health effects

Not available.

Conclusion/Summary : aHAVM Lite Reagent Not available.
aHAVM Solid Phase Reagent Not available.
aHAVM Ancillary Well Reagent Not available.
aHAVM Ancillary Pack Reagent Not available.
aHAVM Calibrator Hi Not available.
aHAVM Calibrator Lo Not available.

General : aHAVM Lite Reagent No known significant effects or critical hazards.
aHAVM Solid Phase Reagent No known significant effects or critical hazards.
aHAVM Ancillary Well Reagent No known significant effects or critical hazards.
aHAVM Ancillary Pack Reagent No known significant effects or critical hazards.
aHAVM Calibrator Hi Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
aHAVM Calibrator Lo Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity : aHAVM Lite Reagent No known significant effects or critical hazards.
aHAVM Solid Phase Reagent No known significant effects or critical hazards.
aHAVM Ancillary Well Reagent No known significant effects or critical hazards.
aHAVM Ancillary Pack Reagent No known significant effects or critical hazards.
aHAVM Calibrator Hi No known significant effects or critical hazards.
aHAVM Calibrator Lo No known significant effects or critical hazards.

SECTION 11: Toxicological information

Mutagenicity	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
Reproductive toxicity	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards. No known significant effects or critical hazards.
Interactive effects	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
<u>Toxicokinetics</u>		
Absorption	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
Distribution	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
Metabolism	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.
Elimination	: aHAVM Lite Reagent aHAVM Solid Phase Reagent aHAVM Ancillary Well Reagent aHAVM Ancillary Pack Reagent aHAVM Calibrator Hi aHAVM Calibrator Lo	Not available. Not available. Not available. Not available. Not available. Not available.

Atellica® IM Hepatitis A IgM (aHAVM)

SECTION 11: Toxicological information

Other information	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.

SECTION 12: Ecological information

12.1 Toxicity

Conclusion/Summary	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.

12.2 Persistence and degradability

Conclusion/Summary	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc})	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.
Mobility	: aHAVM Lite Reagent	Not available.
	aHAVM Solid Phase Reagent	Not available.
	aHAVM Ancillary Well Reagent	Not available.
	aHAVM Ancillary Pack Reagent	Not available.
	aHAVM Calibrator Hi	Not available.
	aHAVM Calibrator Lo	Not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

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

SECTION 13: Disposal considerations

- Hazardous waste** : The classification of the product may meet the criteria for a hazardous waste. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.
- Packaging**
- Methods of disposal** : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.
- Special precautions** : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spill material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

ADR/RID

14.1 UN number	aHAVM Lite Reagent	Not regulated.
	aHAVM Solid Phase Reagent	Not regulated.
	aHAVM Ancillary Well Reagent	Not regulated.
	aHAVM Ancillary Pack Reagent	Not regulated.
	aHAVM Calibrator Hi	Not regulated.
	aHAVM Calibrator Lo	Not regulated.
14.2 UN proper shipping name	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-
14.3 Transport hazard class(es)	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-
14.4 Packing group	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-
14.5 Environmental hazards	aHAVM Lite Reagent	No.
	aHAVM Solid Phase Reagent	No.
	aHAVM Ancillary Well Reagent	No.
	aHAVM Ancillary Pack Reagent	No.
	aHAVM Calibrator Hi	No.
	aHAVM Calibrator Lo	No.
Additional information	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

ADN

14.1 UN number

Atellica® IM Hepatitis A IgM (aHAVM)

SECTION 14: Transport information

	aHAVM Lite Reagent	Not regulated.
	aHAVM Solid Phase Reagent	Not regulated.
	aHAVM Ancillary Well Reagent	Not regulated.
	aHAVM Ancillary Pack Reagent	Not regulated.
	aHAVM Calibrator Hi	Not regulated.
	aHAVM Calibrator Lo	Not regulated.

14.2 UN proper shipping name	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

14.3 Transport hazard class(es)	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

14.4 Packing group	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

14.5 Environmental hazards	aHAVM Lite Reagent	No.
	aHAVM Solid Phase Reagent	No.
	aHAVM Ancillary Well Reagent	No.
	aHAVM Ancillary Pack Reagent	No.
	aHAVM Calibrator Hi	No.
	aHAVM Calibrator Lo	No.

Additional information	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

IMDG

14.1 UN number	aHAVM Lite Reagent	Not regulated.
	aHAVM Solid Phase Reagent	Not regulated.
	aHAVM Ancillary Well Reagent	Not regulated.
	aHAVM Ancillary Pack Reagent	Not regulated.
	aHAVM Calibrator Hi	Not regulated.
	aHAVM Calibrator Lo	Not regulated.

14.2 UN proper shipping name	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

Atellica® IM Hepatitis A IgM (aHAVM)

SECTION 14: Transport information

14.3 Transport hazard class(es)	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

14.4 Packing group	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

14.5 Environmental hazards	aHAVM Lite Reagent	No.
	aHAVM Solid Phase Reagent	No.
	aHAVM Ancillary Well Reagent	No.
	aHAVM Ancillary Pack Reagent	No.
	aHAVM Calibrator Hi	No.
	aHAVM Calibrator Lo	No.

Additional information	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

IATA

14.1 UN number	aHAVM Lite Reagent	Not regulated.
	aHAVM Solid Phase Reagent	Not regulated.
	aHAVM Ancillary Well Reagent	Not regulated.
	aHAVM Ancillary Pack Reagent	Not regulated.
	aHAVM Calibrator Hi	Not regulated.
	aHAVM Calibrator Lo	Not regulated.

14.2 UN proper shipping name	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

14.3 Transport hazard class(es)	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

14.4 Packing group	aHAVM Lite Reagent	-
	aHAVM Solid Phase Reagent	-
	aHAVM Ancillary Well Reagent	-
	aHAVM Ancillary Pack Reagent	-
	aHAVM Calibrator Hi	-
	aHAVM Calibrator Lo	-

14.5 Environmental hazards

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SECTION 14: Transport information

aHAVM Lite Reagent	No.
aHAVM Solid Phase Reagent	No.
aHAVM Ancillary Well Reagent	No.
aHAVM Ancillary Pack Reagent	No.
aHAVM Calibrator Hi	No.
aHAVM Calibrator Lo	No.

Additional information

aHAVM Lite Reagent	-
aHAVM Solid Phase Reagent	-
aHAVM Ancillary Well Reagent	-
aHAVM Ancillary Pack Reagent	-
aHAVM Calibrator Hi	-
aHAVM Calibrator Lo	-

14.6 Special precautions for user

aHAVM Lite Reagent	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.
aHAVM Solid Phase Reagent	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.
aHAVM Ancillary Well Reagent	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.
aHAVM Ancillary Pack Reagent	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.
aHAVM Calibrator Hi	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.
aHAVM Calibrator Lo	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

UK (GB) /REACH

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Ozone depleting substances

Not listed.

Prior Informed Consent (PIC)

Not listed.

Persistent Organic Pollutants

Not listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	: aHAVM Lite Reagent	Not applicable.
	aHAVM Solid Phase Reagent	Not applicable.
	aHAVM Ancillary Well Reagent	Not applicable.
	aHAVM Ancillary Pack Reagent	Not applicable.
	aHAVM Calibrator Hi	Not applicable.
	aHAVM Calibrator Lo	Not applicable.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

EU regulations

Industrial emissions (integrated pollution prevention and control) - Air	: aHAVM Lite Reagent	Not listed
	aHAVM Solid Phase Reagent	Not listed
	aHAVM Ancillary Well Reagent	Not listed
	aHAVM Ancillary Pack Reagent	Not listed
	aHAVM Calibrator Hi	Not listed
	aHAVM Calibrator Lo	Not listed
Industrial emissions (integrated pollution prevention and control) - Water	: aHAVM Lite Reagent	Not listed
	aHAVM Solid Phase Reagent	Not listed
	aHAVM Ancillary Well Reagent	Not listed
	aHAVM Ancillary Pack Reagent	Not listed
	aHAVM Calibrator Hi	Not listed
	aHAVM Calibrator Lo	Not listed

International regulations

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

15.2 Chemical safety assessment : Not applicable.

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SECTION 16: Other information

✔ Indicates information that has changed from previously issued version.

Abbreviations and acronyms

: ATE = Acute Toxicity Estimate
 GB CLP = UK CLP (EC No 1272/2008) on the Classification, Labelling and Packaging of Substances and Mixtures as amended by (EU Exit) Regulations 2019 No. 720 and amendments
 DMEL = Derived Minimal Effect Level
 DNEL = Derived No Effect Level
 EUH statement = GB CLP-specific Hazard statement
 N/A = Not available
 PBT = Persistent, Bioaccumulative and Toxic
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number
 SGG = Segregation Group
 vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification

Classification	Justification
aHAVM Calibrator Hi Skin Sens. 1, H317 Aquatic Chronic 3, H412	Calculation method Calculation method
aHAVM Calibrator Lo Skin Sens. 1, H317 Aquatic Chronic 3, H412	Calculation method Calculation method

Full text of abbreviated H statements

aHAVM Calibrator Hi	
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.
aHAVM Calibrator Lo	
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

Full text of classifications

Atellica® IM Hepatitis A IgM (aHAVM)

SECTION 16: Other information

aHAVM Calibrator Hi

Acute Tox. 2	ACUTE TOXICITY - Category 2
Acute Tox. 3	ACUTE TOXICITY - Category 3
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Aquatic Chronic 3	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Skin Corr. 1C	SKIN CORROSION/IRRITATION - Category 1C
Skin Sens. 1	SKIN SENSITISATION - Category 1
Skin Sens. 1A	SKIN SENSITISATION - Category 1A

aHAVM Calibrator

Lo

Acute Tox. 2	ACUTE TOXICITY - Category 2
Acute Tox. 3	ACUTE TOXICITY - Category 3
Aquatic Acute 1	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Aquatic Chronic 3	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3
Eye Dam. 1	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1
Skin Corr. 1C	SKIN CORROSION/IRRITATION - Category 1C
Skin Sens. 1	SKIN SENSITISATION - Category 1
Skin Sens. 1A	SKIN SENSITISATION - Category 1A

Date of printing	: 12/13/2022
Date of issue/ Date of revision	: 12/13/2022
Date of previous issue	: No previous validation
Version	: 1

Notice to reader

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

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