

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Finished product
Trade name	: Allplex™ RV Master Assay
Product code	: RV10307X, RV10363Z
Type of product	: Reagents and laboratory chemicals
Product group	: End product

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

Main use category	: In vitro diagnostics (IVD)
Use of the substance/mixture	: Comply with instructions for use (refer to technical sheet)
Function or use category	: For professional use only

Uses advised against

Restrictions on use	: Restricted to professional users
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1.3. Details of the supplier of the safety data sheet

Seegene Inc.
Taewon Bldg., 91, Ogeum-ro, Songpa-Gu, Seoul, Republic of Korea 05548
T +82-2-2240-4000, F +82-2-2240-4040
info@seegene.com, <https://www.seegene.com>

1.4. Emergency telephone number

Emergency number	: +82-2-2195-6596 (E-mail: sg_sds@seegene.com)
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SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Specific target organ toxicity – Single exposure, Category 2 H371

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP)



GHS08

Signal word (CLP)	: Warning
Contains	: Tetramethylammonium chloride
Hazard statements (CLP)	: H371 - May cause damage to organs.
Precautionary statements (CLP)	: P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor. P405 - Store locked up. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
SEM XR1			
Glycerol substance with national workplace exposure limit(s) (DE, ES, FR)	CAS-No.: 56-81-5 EC-No.: 200-289-5	15 – 20	Not classified
SEM XR1 buffer			
Glycerol substance with national workplace exposure limit(s) (DE, ES, FR)	CAS-No.: 56-81-5 EC-No.: 200-289-5	1 – 5	Not classified
Tetramethylammonium chloride	CAS-No.: 75-57-0 EC-No.: 200-880-8	1.5 – 2	Acute Tox. 2 (Oral), H300 (ATE=47 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE=200 mg/kg bodyweight) Skin Irrit. 2, H315 STOT SE 1, H370 Aquatic Chronic 2, H411

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Get medical advice/attention if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.
First-aid measures for first aider	: First aid workers will be equipped with suitable personal protective equipment.

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

Symptoms/effects after inhalation	: Although no appropriate human or animal health effects data are known to exist, this material is expected to be an inhalation hazard.
Symptoms/effects after skin contact	: None under normal conditions.
Symptoms/effects after eye contact	: None under normal conditions.
Symptoms/effects after ingestion	: None under normal conditions.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: No fire hazard.
Explosion hazard	: No direct explosion hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions	: Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Stop leak if safe to do so. Notify authorities if product enters sewers or public waters.
Absorb spillage to prevent material damage.

For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.
Emergency procedures : Ventilate spillage area. Do not breathe dust/fume/gas/mist/vapours/spray.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures : Evacuate unnecessary personnel. Stop leak if safe to do so.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Absorb spilled material with sand or earth. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Stop leak without risks if possible.
Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.
Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Do not breathe dust/fume/gas/mist/vapours/spray.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed and at a temperature not exceeding -20°C.
Packaging materials : Store always product in container of same material as original container.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

National occupational exposure and biological limit values

Glycerol (56-81-5)	
France - Occupational Exposure Limits	
Local name	Glycérine (aérosols de)
VME (OEL TWA)	10 mg/m ³
Remark	Valeurs recommandées/admises
Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 6443, 2022; Outil65)
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	Glycerin
AGW (OEL TWA)	200 mg/m ³ (E)
Peak exposure limitation factor	2(I)

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Glycerol (56-81-5)	
Remark	DFG - Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission); Y - Ein Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes (BGW) nicht befürchtet zu werden
Regulatory reference	TRGS900
Spain - Occupational Exposure Limits	
Local name	Glicerina
VLA-ED (OEL TWA)	10 mg/m ³ nieblas
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2024. INSHT

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment.

Eye and face protection

Eye protection			
Type	Field of application	Characteristics	Standard
Safety glasses	Chemical substance	With side shields	EN 166

Skin protection

Skin and body protection:

Wear a lab coat.

Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Disposable gloves	Nitrile rubber (NBR), Latex	4 (> 120 minutes)	0.05	2 (< 1.5)	EN455 1-4

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Not available
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available

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Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

Glycerol (56-81-5)	
LD50 oral rat	27200 mg/kg bodyweight Animal: rat, Animal sex: female
LC50 Inhalation - Rat	5.85 mg/l air Animal: rat

Tetramethylammonium chloride (75-57-0)	
LD50 oral rat	47 mg/kg
LD50 dermal rabbit	200 – 500 mg/kg bodyweight Animal: rabbit, Guideline: OECD Guideline 402 (Acute Dermal Toxicity)

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified

Tetramethylammonium chloride (75-57-0)	
NOAEL (animal/female, F0/P)	5 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)

STOT-single exposure : May cause damage to organs.

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Tetramethylammonium chloride (75-57-0)	
STOT-single exposure	Causes damage to organs.
STOT-repeated exposure	: Not classified

Tetramethylammonium chloride (75-57-0)	
NOAEL (oral, rat, 90 days)	10 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents), Guideline: EU Method B.26 (Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents), Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
Aspiration hazard	: Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

Glycerol (56-81-5)	
LC50 - Fish [1]	54000 mg/l Source: ECHA

Tetramethylammonium chloride (75-57-0)	
LC50 - Fish [1]	462 mg/l Test organisms (species): Pimephales promelas
EC50 - Crustacea [1]	3 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	96.3 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)

12.2. Persistence and degradability

Allplex™ RV Master Assay	
Persistence and degradability	Not rapidly degradable

12.3. Bioaccumulative potential

Glycerol (56-81-5)	
Partition coefficient n-octanol/water (Log Pow)	-1.75 Source: ECHA

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Disposal must be done according to official regulations.
Additional information	: Do not re-use empty containers.
HP Code	: HP5 - "Specific Target Organ Toxicity (STOT)/Aspiration Toxicity:" waste which can cause specific target organ toxicity either from a single or repeated exposure, or which cause acute toxic effects following aspiration. HP6 - "Acute Toxicity:" waste which can cause acute toxic effects following oral or dermal administration, or inhalation exposure. HP4 - "Irritant – skin irritation and eye damage:" waste which on application can cause skin irritation or damage to the eye.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)		
Reference code	Applicable on	Entry title or description
3(b)	Allplex™ RV Master Assay ; Tetramethylammonium chloride	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10
3(c)	Tetramethylammonium chloride	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

National regulations

Germany

- Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG).
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
- Water hazard class (WGK) : WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1).
- Storage class (LGK, TRGS 510) : LGK 12 - Non-combustible liquids.
- Joint storage table :
- | | | | | |
|----------|---------|----------|----------|-----------|
| LGK 1 | LGK 2A | LGK 2B | LGK 3 | LGK 4.1A |
| LGK 4.1B | LGK 4.2 | LGK 4.3 | LGK 5.1A | LGK 5.1B |
| LGK 5.1C | LGK 5.2 | LGK 6.1A | LGK 6.1B | LGK 6.1C |
| LGK 6.1D | LGK 6.2 | LGK 7 | LGK 8A | LGK 8B |
| LGK 10 | LGK 11 | LGK 12 | LGK 13 | LGK 10-13 |
- Joint storage not permitted for : LGK 1, LGK 6.2, LGK 7.
- Joint storage with restrictions permitted for : LGK 4.1A, LGK 4.3, LGK 5.1C.
- Joint storage permitted for : LGK 2A, LGK 2B, LGK 3, LGK 4.1B, LGK 4.2, LGK 5.1A, LGK 5.1B, LGK 5.2, LGK 6.1A, LGK 6.1B, LGK 6.1C, LGK 6.1D, LGK 8A, LGK 8B, LGK 10, LGK 11, LGK 12, LGK 13, LGK 10-13.
- Hazardous Incident Ordinance (12. BImSchV) : Is not subject to the Hazardous Incident Ordinance (12. BImSchV)

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Netherlands

- ABM category : A(4) - low hazard for aquatic organisms, may have longterm hazardous effects in aquatic environment
- SZW list of carcinogens : None of the components are listed
- SZW list of mutagens : None of the components are listed
- SZW list of reprotoxic substances – Breastfeeding : None of the components are listed
- SZW list of reprotoxic substances – Fertility : None of the components are listed
- SZW list of reprotoxic substances – Development : None of the components are listed

Denmark

- Danish National Regulations : Young people below the age of 18 years are not allowed to use the product
Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Poland

- Polish National Regulations : Act of 25 February 2011 on chemical substances and their mixtures (J. o L. No. 63, item 322 as amended; consolidated text J. o L. 2019, item 1225).
Act of 14 December 2012 on waste (J. o L. 2013, item 322 as amended; consolidated text J. o L. 2020, item 797).
The announcement of Marshal of the Sejm of the Republic of Poland dated 19 October 2016 concerning the consolidated text announcement of the decree on the management of packaging and packaging waste (J. o L. 2016, item 1863 as amended).
Decree of the Minister of Environment of 14 December 2014 on the catalogue of waste (J. o L. 2014, item 1923).
Act of 19 August 2011 on the Carriage of Dangerous Goods (J. o L. 2011 No. 227, item 1367 as amended; consolidated text J. o L. 2020, item 154).
Regulation of the Minister of Family, Labour and Social Policy of 12 June 2018 on the highest permissible concentration and intensity of noxious agents for health at work environment (J. o L. item 1286 as amended).
The announcement of Minister of Health dated 9 September 2016 concerning the consolidated text announcement of the decree of the Minister of Health of 30 December 2004 on health and safety at work related to exposure to chemical agents at work (J. o L. of 16 September 2016, item 1488)
Regulation of the Minister of Health of 2 February 2011 on tests and measurements of the noxious agents for health at work environment (J. o L. No. 33, item 166 as amended).
Regulation of the Minister of Environment of 9 December 2003 on particularly hazardous substances to the environment (J. o L. No. 217, item 2141).
ADR Agreement: Government Statement of 13 March 2023 on the entry into force of amendments to Annexes A and B to the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), signed in Geneva on 30 September 1957 (J. o. L. 2023, item 891)

Switzerland

- Storage class (LK) : LK 6.1 - Toxic materials

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)

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Abbreviations and acronyms:

COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disruptor

Full text of H- and EUH-statements:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
H300	Fatal if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H370	Causes damage to organs.
H371	May cause damage to organs.

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Full text of H- and EUH-statements:

H411	Toxic to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 1	Specific target organ toxicity – single exposure, Category 1
STOT SE 2	Specific target organ toxicity – Single exposure, Category 2

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

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