

SAFETY DATA SHEET

WIESLAB[®] Complement kits

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

1.1 Product identifier

Product name: WIESLAB[®] Complement System Alternative pathway
 WIESLAB[®] Complement System Classical pathway
 WIESLAB[®] Complement System MBL pathway
 WIESLAB[®] Complement System Screen

Product description

Kit consisting of following reagents:

- Antigen-coated plates, CP, MP and AP
- Dilution Buffer CP
- Dilution Buffer MP
- Dilution Buffer AP
- Wash Solution (30x Conc.)
- Conjugate Solution
- Positive Control
- Negative Control
- Substrate pNPP
- Activity Control (for Classic Pathway)

Product code

COMPL AP 330, COMPL AP 330 RUO
COMPL CP 310, COMPL CP 310 RUO
COMPL MP 320, COMPL MP 320 RUO
COMPL 300, COMPL 300 RUO

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

Use of the product Kit consisting of different reagents for in vitro diagnostic and research use.

1.3 Details of the Supplier of the safety data sheet

Company Svar Life Science AB
Address Lundvägen 151
Zip code/Place SE-212 24 Malmö, Sweden
Telephone +46 40 53 76 00
Website www.svarlifescience.com
E-mail info@svarlifescience.com

1.4 Emergency telephone number

Emergency telephone number (Sweden) Acute: 112 – Ask for "Giftinformation". If less acute call: +46 010 4566700.
 (UK) NHS (England or Wales): Dial 111 or 0845 4647 NHS 24
 (Scotland): 08454 24 24 24

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to the Regulation (EC) No. 1272/2008 (CLP)

Wash Solution (30x Conc.): Skin Sens.1; H317 Aquatic Chronic 3; H412

The remaining reagents are not classified as dangerous.

2.2 Label elements

Wash Solution (30x Conc.)



WARNING

Contains: 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)

| | |
|-------------|--|
| H317 | May cause an allergic skin reaction |
| H412 | Harmful to aquatic life with long lasting effects. |
| P261 | Avoid breathing spray. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves. |
| P333 + P313 | If skin irritation or rash occurs: Get medical advice/attention. |

Dilution Buffer CP, Dilution Buffer MP, Dilution Buffer AP, Conjugate Solution, Negative Control, Substrate pNPP

| | |
|---------|---|
| EUH208 | Contains "Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)" May produce an allergic reaction. |
| EUH210: | Safety data sheet available on request. |

The remaining reagents require no CLP labelling.

2.3 Other hazards

Other hazards which do not result in classification Contain serum which is derived from human. The certificate of analysis states that the serum has been tested for hepatitis B, hepatitis C and antibodies for HIV, and found to be negative. The products are considered as biological agents in group 2.



Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII

PBT: No

Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII

vPvB: No

Endocrine disrupting properties

The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2017/2100 or Regulation 2018/605.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

The products listed under section 1.1 contain the following declarable preservative unless specified otherwise.

| Product/ingredient name | EC-number | CAS-number | REACH registration number | Conc. (weight-%) | Classification Regulation (EC) No. 1272/2008 [CLP] |
|---|-----------|------------|---------------------------|------------------|---|
| Wash Solution (30x Conc.) | | | | | |
| CMI/MI* (Index No.: 613-167-00-5) | - | 55965-84-9 | - | <0.015 | Acute Tox. 3; H301 (ATE = 100mg/kg) Acute Tox. 2; H310 (ATE = 50mg/kg) Acute Tox. 3; H331 (ATE = 0,05mg/l/4H) Eye Dam. 1; H318 Skin Corr. 1C; H314 SCL: Skin Corr. 1C; H314: C ≥ 0,6% Eye Dam. 1; H318: C ≥ 0,6% Eye Irrit. 2; H319: 0,06% < C < 0,6% Skin Irrit. 2; H315: 0,06% < C < 0,6% Skin Sens. 1A; H317 (SCL = 0.0015%) Aquatic Acute 1; H400 (M = 100) Aquatic Chronic 1; H410 (M = 100) |
| Dilution Buffer CP, Dilution Buffer MP, Dilution Buffer AP, Conjugate Solution, Negative Control, Substrate pNPP | | | | | |
| CMI/MI* (Index No.: 613-167-00-5) | - | 55965-84-9 | - | <0.0015 | Acute Tox. 3; H301 (ATE = 100mg/kg) Acute Tox. 2; H310 (ATE = 50mg/kg) Acute Tox. 3; H331 (ATE = 0,05mg/l/4H) Eye Dam. 1; H318 Skin Corr. 1C; H314 SCL: Skin Corr. 1C; H314: C ≥ 0,6% Eye Dam. 1; H318: C ≥ 0,6% Eye Irrit. 2; H319: 0,06% < C < 0,6% Skin Irrit. 2; H315: 0,06% < C < 0,6% Skin Sens. 1A; H317 (SCL = 0.0015%) Aquatic Acute 1; H400 (M = 100) Aquatic Chronic 1; H410 (M = 100) |

* CMI/MI = 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)

Antigen-coated plates, Positive Control and Activity Control reagents contain no declarable substances.

See section 16 for the full text of the classifications declared above.

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|----------------------|--|
| Inhalation: | Remove to fresh air, rest. Call a physician if the complaints persist. |
| Skin contact: | Remove contaminated clothing and footwear. Wash the skin properly with soap and water. |
| Eye contact: | Keep eyelids well apart. Rinse with water for a couple of minutes. Call a physician if the complaints persist. |
| Ingestion | Wash mouth properly with water. If victim is conscious and alert, give 2-4 cupfuls of milk/water to dilute the substance in stomach. Call a physician if the complaints persist. |

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

| | |
|----------------------|---|
| Inhalation: | Exposure to high airborne concentrations of the reagents in this kit may cause irritation in the respiratory tract, dizziness and sickness. |
| Skin contact: | Exposure to the skin may cause an allergic skin reaction. |
| Eye contact: | May cause mild eye irritation. |
| Ingestion: | Ingestion of larger amounts may cause sickness and vomiting. |

4.3 Indication of any immediate medical attention and special treatment needed

Ingestion: Treat symptomatically.
Specific treatments: No specific treatment.

SECTION 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media Dry chemical, foam, water spray or carbon dioxide.
Unsuitable extinguishing media Waterjet

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture None
Hazardous thermal decomposition products Decomposition products may include the following materials: carbon monoxide, carbon dioxide and nitrous gases.

5.3 Advice for firefighters

Special protective actions for fire-fighters Not relevant. The product will not burn.
Special protective equipment for fire-fighters Not Applicable.
Further information Not applicable

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep non-emergency personnel away from the spillage area..
For emergency responders 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 Section 8 for additional information on hygiene measures.

6.2 Environmental precautions

Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.

6.3 Methods and materials 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 The kit only contains small amounts of each reagent.

6.4 Reference to other sections

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). |
| 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

| | |
|-----------------------------|---|
| Storage: | Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10), 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. |
| Further information: | Not applicable |

7.3 Specific end use(s)

Reagents for in vitro diagnostic and research use.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits

| Chemical name | EU | United Kingdom | France | Spain | Germany |
|--------------------------------|---------|----------------|-------------|---------|---------|
| CMI/MI (CAS No. 55965-84-9) | None. | None. | None. | None. | None. |
| Chemical name | Italy | Portugal | Netherlands | Finland | Denmark |
| CMI/MI (CAS No. 55965-84-9) | None. | None. | None. | None. | None. |
| Chemical name | Austria | Switzerland | Poland | Norway | Ireland |
| CMI/MI (CAS No. 55965-84-9) | None. | None. | None. | None. | None. |

Recommended monitoring procedure Not relevant

Derived effect levels

| Product/ingredient name | Type | Exposure | Value | Population | Effects |
|-------------------------|------|----------|-------|------------|---------|
| -- | -- | -- | -- | -- | -- |

Predicted effect concentrations Not available

PNEC Summary Not available

8.2 Exposure controls

Appropriate engineering controls Good general ventilation should be sufficient to control worker exposure to airborne contaminants. Otherwise, use local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

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

| | |
|---------------------------------------|--|
| Respiratory protection | Not relevant during normal condition. |
| Eye/face protection | Use safety glasses (according to EN166) when there is risk of splashes. |
| Hand protection | Wear protective gloves (according to EN374) of butyl rubber or nitrile rubber. |
| Body protection | Wear suitable protective clothing. |
| Environmental exposurecontrols | Not applicable |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties of the reagents

| | Dilution buffer | Wash solution | Conjugate solution | Positive control, Activity control | Negative control | Substrate pNPP |
|---|------------------|------------------|--------------------|------------------------------------|------------------|------------------|
| Physical state | Liquid | Liquid | Liquid | Lyophilized PC and AC | Liquid | Liquid |
| Colour | Colourless | Colourless | Blue | Colourless | Colourless | Colourless |
| Odour | Odourless | Odourless | Odourless | Odourless | Odourless | Odourless |
| Melting point/freezing point | n.d | n.d | n.d | n.d | n.d | n.d |
| Boiling point or initial boiling point and boiling range | n.d | n.d | n.d | n.d | n.d | n.d |
| Flammability (solid, gas) | n.a | n.a | n.a | n.a | n.a | n.a |
| Lower and upper explosion limit | n.a | n.a | n.a | n.a | n.a | n.a |
| Flash point | > 100°C | > 100°C | > 100°C | > 100°C | > 100°C | > 100°C |
| Auto-ignition temperature | n.d | n.d | n.d | n.d | n.d | n.d |
| Decomposition temperature | n.d | n.d | n.d | n.d | n.d | n.d |
| pH | 7.3 - 7.5 | 6.5-8.0 | 7.4 - 7.6 | n.d | n.d | 9.55 - 9.65 |
| Kinematic viscosity | n.d | n.d | n.d | n.d | n.d | n.d |
| Solubility | Soluble in water | Soluble in water | Soluble in water | Soluble in water | Soluble in water | Soluble in water |
| Partition coefficient n-octanol/water (log value): | n.a | n.a | n.a | n.a | n.a | n.a |
| Vapour pressure | n.d | n.d | n.d | n.d | n.d | n.d |
| Density and/or relative density | n.d | n.d | n.d | n.d | n.d | n.d |
| Relative vapour density: | n.a | n.a | n.a | n.a | n.a | n.a |
| Particle characteristics: | n.a | n.a | n.a | n.a | n.a | n.a |

n.a = not applicable. n.d = not determined

9.2 Other information

Not applicable

SECTION 10. STABILITY AND REACTIVITY

| | |
|--|---|
| 10.1 Reactivity | Non-reactive |
| 10.2 Chemical stability | Stabile under normal conditions of use and storage. |
| 10.3 Possibility of hazardous reactions | Under normal conditions of storage and use, hazardous reactions will not occur. |
| 10.4 Condition to avoid | Avoid direct sunlight. |
| 10.5 Incompatible materials | None |
| 10.6 Hazardous decomposition products | Carbon monoxide, carbon dioxide and nitrous gases. |

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Based on available data, the classification criteria are not met.

Calculated data:

LD₅₀ oral, rat: > 2000 mg/kg

LD₅₀ dermal, rat: > 2000 mg/kg

Irritation/Corrosion

Based on available data, the classification criteria are not met.

Experimental/calculated data: Corrosive or irritating to the skin, rabbit: Not irritating.

Serious eye damage/irritation

Based on available data, the classification criteria are not met.

Experimental/calculated data: Serious eye damage/eye irritation, rabbit: Not irritating.

Respiratory or skin sensitization

Skin Sens. 1;H317 May cause an allergic skin reaction.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

None known.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Acute toxicity in the aquatic environment for CMI/MI

| Test | Value/unit (mg/l) | Test method | Exp. time (h) | Species |
|--------------------------|-------------------|-------------|---------------|-------------------|
| Fish LC ₅₀ | 0.19 | -- | 96 | Salmo gairdneri |
| Daphnia EC ₅₀ | 0.028 | -- | 48 | Crassostrea virg. |
| Algea EC ₅₀ | 0.018 | -- | 96 | Selenastrum cap. |

12.2 Persistence and degradability

Conclusion/Summary CMI/MI is not rapidly degradable

12.3 Bioaccumulative potential

Conclusion/Summary CMI/MI: Log Kow > 5 (significant bioaccumulation).

12.4 Mobility in soil

Soil/water partition coefficient (KOC) Not available

Mobility Not available

12.5 Results of PBT and vPvB assessment

PBT Not applicable

vPvB Not applicable

12.6 Endocrine disrupting properties

Conclusion None known.

12.7 Other adverse effects

Conclusion None known.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Method of disposal The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. 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.

Used kit may be potentially infectious material and shall be disposed as a hazardous waste.

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

Used kit may be potentially infectious material and shall be disposed as a hazardous waste.

European Waste Catalogue (EWC)

| EWC Waste Code | Type of waste |
|----------------|---|
| 18 01 07 | Product |
| 15 02 03 | Absorbents, filter materials, wiping cloths and protective clothing |
| 18 01 03 | Used kit |

Packaging

Method of disposal Incineration.

Special precautions None.

SECTION 14. TRANSPORT INFORMATION

Product classified as dangerous goods: Yes No Not decided

| | ADR/RID | ADN/ADNR | IMDG | IATA |
|---|--|----------------|----------------|----------------|
| 14.1 UN number or ID number | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.2 UN proper shipping name | -- | -- | -- | -- |
| 14.3 Transport hazard class(es) | -- | -- | -- | -- |
| 14.4 Packing Group | -- | -- | -- | -- |
| 14.5 Environmental hazards | -- | -- | -- | -- |
| 14.6 Special precautions for user | Not available | Not available | Not available | Not available |
| 14.7 Maritime transport in bulk according to IMO instruments | Not applicable | Not applicable | Not applicable | Not applicable |
| Additional information | Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for further information. | | | |

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health, and environmental regulations/legislation specific for the substance or mixture EU Regulation (EC) No. 1907/2006 (REACH), Directive 2000/54/EC – Biological agents at work

REACH Status In compliance.
Pre-registration status: All components are listed or exempted.

**Annex XIV - List of substances subject to authorization
Substances of very high concern**

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures, and articles

Not applicable.

15.2 Chemical safety assessment

The reagents in this kit contain substances for which Chemical Safety Assessments still are required.

15.3 Other information

Tariff Code – harmonized system Not applicable

The EU Seveso Directive Not applicable

International regulations

**Chemical Weapons Convention List
Schedule I Chemicals**
Not regulated

**Chemical Weapons Convention List
Schedule II Chemicals**
Not regulated

**Chemical Weapons Convention List
Schedule III Chemicals**
Not regulated

SECTION 16. OTHER INFORMATION

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II

Disclaimer: The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

THE PRODUCER'S NOTES

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LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3

| No. | H-Statements |
|------|---|
| H301 | Toxic if swallowed. |
| H310 | Fatal if in contact with skin. |
| H331 | Toxic if inhaled. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| 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. |

DOCUMENT HISTORY

| Version | Valid from (date) | Changes |
|---------|-------------------|---|
| 1.0 | 16-May-2022 | New document. Format updates according to Regulation 2020/878. |
| 2.0 | 14-Nov-2022 | Correction of content of Procline in Wash solution, to 5.0 ml/l, leading to classification of Wash solutions as allergenic and dangerous for environment. Updates in sections 2.1, 2.2, 3.2 and 16. |
| 3.0 | 11-May-2023 | Correction of document version number |