


Monolisa™ HAV IgM PLUS

2 plates -  192

 72491

KIT FOR DETECTION OF ANTI-HAV IgM IN SERUM/PLASMA
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1 - INTENDED USE

Monolisa™ HAV IgM PLUS is an enzyme immunoassay kit for the qualitative detection of anti-HAV IgM antibodies in human serum or plasma.

Appearance of anti-HAV IgM antibodies in the circulation demonstrates a recent exposure to Hepatitis A Virus (HAV). IgM antibodies anti-HAV appear a few days after infection and persist at elevated levels in the bloodstream for few months. However, sensitive immunoassays occasionally detect IgM for up to one year after acute hepatitis.

2 - PRINCIPLE OF THE TEST

Monolisa™ HAV IgM PLUS is enzyme immuno-assay based on the capture of sample IgM antibodies on microplates coated with polyclonal antibody to human IgM.

1. First, sample is added into the microwell with diluent and incubated for 1 hour at 37°C. Excess of sample is removed by a wash step at the end of the incubation.
2. A first reagent containing HAV viral antigen and a second reagent with enzyme tracer (containing horseradish peroxidase-labelled mouse monoclonal antibody to HAV) are successively added to the well then incubated for 1 hour at 37°C. The presence of IgM anti-HAV enables the HAV and the enzyme tracer to bind to the solid phase.
3. Excess of enzyme tracer and HAV are removed by a wash step, and TMB chromogen/substrate solution is added into each well.
4. After 30 minutes of incubation at room temperature, the reaction is stopped and the reading is made spectrophotometrically at 450/620-700 nm. Measured absorbance for one sample allows the determination of the presence or the absence of IgM anti-HAV antibodies in the tested sample. Colour intensity is proportional to the quantity of IgM anti-HAV antibodies bounded to the solid phase.

3 - COMPOSITION OF THE KIT

Identification on label		Description	Presentation/ Preparation 72491
R1	Microplate	Microplate 12 strips of 8 wells coated with polyclonal anti-IgM antibodies	2 plates
R2	Concentrated washing solution (20X)	Concentrated washing solution (20X) Tris NaCl buffer, pH 7.4 Preservative: ProClin™ 300 (0.04%)	1 vial 235 ml
R3	Negative control	Negative control Human plasma, negative for IgM anti-HAV Antibodies, for total anti-HAV Antibodies, for HBs Antigen, for anti-HCV antibodies and for anti-HIV 1-2 antibodies Preservative: Sodium azide (< 0.1%)	1 vial 1 ml
R4	Positive cut-off	Positive cut-off Human plasma, positive for IgM anti-HAV Antibodies and negative for HBs Antigen, for anti-HCV antibodies and for anti-HIV 1-2 antibodies, diluted in coloured synthetic base Preservative: Sodium azide (< 0.1%), Proclin™ 300 (0.1%)	1 vial 1.6 ml
R5	Positive control	Positive control Human plasma, positive for IgM anti-HAV Antibodies and negative for HBs Antigen, for anti-HCV antibodies and for anti-HIV 1-2 antibodies, diluted in human plasma pool negative for anti-HAV antibodies Preservative: Sodium azide (< 0.1%)	1 vial 1 ml
R6	Specimen diluent	Specimen diluent Tris buffer containing protein and sample indicator dye Preservative agent: ProClin™ 300 (0.1%)	1 vial 21 ml
R7a	HAV viral antigen	HAV viral antigen Tris buffer containing protein, inactivated HAV virus and sample indicator dye Preservative agent: ProClin™ 300 (0.1%)	1 vial 13 ml
R7b	Conjugate	Conjugate: monoclonal.Anti-HAV (mouse) - Peroxidase Tris buffer containing proteins, detergent with conjugate (peroxidase-labelled mouse monoclonal antibody to HAV) and sample indicator dye Preservative agent: ProClin™ 300 (0.1%)	1 vial 13 ml
R8	Substrate buffer	Substrate buffer Citric acid and Sodium acetate solution pH 4.0 containing H ₂ O ₂ (0.015%) and dimethyl sulfoxide (DMSO) 4%	1 vial 60 ml
R9	Chromogen: TMB solution (11X)	Chromogen Solution containing 3.3', 5.5' tetramethylbenzidine (TMB)	1 vial 5 ml
R10	Stopping solution	Stopping solution Sulphuric acid solution (H ₂ SO ₄ 1N)	1 vial 28 ml

4 - MATERIAL REQUIRED BUT NOT PROVIDED

- Distilled or deionized water.
- Sodium hypochlorite (bleach) and sodium bicarbonate.
- Absorbent paper.
- Disposable gloves.
- Protective glasses.
- Disposable tubes.
- Automatic or semi-automatic adjustable or fixed pipettes capable of delivering 50 µl, 80 µl, 100 µl, 200 µl and 1 ml.
- Graduated cylinders of 10 ml, 200 ml and 1000 ml capacity.
- Vortex mixer.
- Automatic*, semi-automatic* or manual microplate washing system.
- Water bath or Dry incubator*, thermostatically set at 37°C ± 1°C.
- Container for contaminated residues.
- Microplate reading device* (equipped with 450, 490, 620, 450/620 to 700 nm filters).

(*) Contact your representative for further information on the equipment validated by our technical services.

5 - HEALTH AND SAFETY INSTRUCTIONS

All the reagents included in the kit are intended for "in vitro" diagnostic use.

- The name of the test, as well as a specific identification number for the test, are written on the frame of each microtiterplate. This specific identification number is stated on each strip too.

Monolisa™ HAV IgM PLUS : Specific ID number = 58.

Verify the specific identification number before use. If the identification number is missing, or different from the stated number above, the strip should not be used.

- Wear disposable gloves when handling reagents and samples and thoroughly wash your hands after having handled them.
- Do not pipette by mouth.
- Human source material used in the preparation of negative control (R3), positive control (R5) and positive cut-off (R4) has been tested and found non-reactive for hepatitis B surface antigen (HBs Ag), antibodies to Hepatitis C Virus (HCV) and antibodies to Human Immunodeficiency Viruses (HIV-1 and HIV-2 Ab). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious diseases.
- Consider any material directly in contact with samples and reagents of human origin, as well as washing solutions, as infectious materials.
- Avoid spilling samples or solutions containing samples.
- Spills must be rinsed with bleach diluted to 10%. If the contaminating fluid is an acid, spills must be initially neutralized with sodium bicarbonate, then cleaned with bleach and dried with absorbent paper. The material used for cleaning must be discarded in a contaminated residue container.
- Samples, reagents of human origin, as well as contaminated material and products should be discarded after decontamination
 - either by immersion in bleach at the final concentration of 5% of sodium hypochlorite (1 volume of bleach for 10 volumes of contaminated fluid or water) for 30 minutes,
 - or by autoclaving at 121°C for 2 hours minimum.

CAUTION: DO NOT INTRODUCE SOLUTIONS CONTAINING SODIUM HYPOCHLORITE INTO THE AUTOCLAVE.

- Avoid any contact of the substrate buffer, the chromogen and the stop solution with the skin or mucosa.
- Do not forget to neutralize and/or autoclave the solutions or washing wastes or any fluid containing biological samples before discarding them into the sink.
- For hazard and precaution recommendations related to some chemical components in this test kit, please refer to the pictogram(s) mentioned on the labels and the information supplied at the end of instruction for use. The Safety Data Sheet is available on www.bio-rad.com.

6 - PRECAUTIONS

The quality of results is dependent upon the following good laboratory practices :

- Do not use expired reagents.
- Do not mix reagents from different lots within a given test run.
REMARK : For washing solution (R2, label identification : 20X coloured green), peroxidase substrate buffer (R8, label identification : TMB buf, coloured blue), chromogen (R9, label identification : TMB 11X, coloured purple) and stopping solution (R10, label identification : 1N coloured red), it is possible to use other lots than those contained in the kit, provided the same lot is used within a given test run. These reagents can be used with some other products of our company. In addition, the wash solution (R2, label identification : **20X coloured green**) can be mixed with the 2 other wash solutions included in various Bio-Rad Reagent kits (R2, label identifications : 10X coloured blue or 10X coloured orange) when properly reconstituted, provided only one mixture is used within a given test run. Contact our technical service for detailed information.
- Before use, wait for 30 minutes for the reagents to stabilize at room temperature.
- Carefully reconstitute the reagents avoiding any contamination.
- Do not carry out the test in the presence of reactive vapours (acid, alkaline, aldehyde vapours) or dust that could alter the enzymatic activity of the conjugate.
- Use glassware thoroughly washed and rinsed with deionized water or preferably, disposable material.
- Do not allow the microplate to dry between the end of the washing operation and the reagent distribution.
- The enzymatic reaction is very sensitive to any metals or metal ions. Consequently, no metal element must be allowed to come into contact with the various solutions that contain conjugate or substrate solution.
- The development solution (substrate buffer + chromogen) must be coloured pink. The modification of this pink colour within a few minutes after reconstitution indicates that the reagent cannot be used and must be replaced.

Preparation of the development solution can be made in a clean disposable single use plastic tray or glass container that has first been pre-washed with 1N HCl and rinsed thoroughly with distilled water and dried. This reagent must be stored in the dark.

- Use a new distribution tip for each serum.
- Well washing is a critical step in this procedure : respect the recommended number of washing cycles and make sure that all wells are completely filled and then completely emptied. Incorrect washing may lead to inaccurate results.
- Never use the same container to distribute the conjugate and the development solution.

7 - SAMPLES

Collect a blood sample according to the usual practice.

The test should be performed on undiluted serum or plasma (collected in EDTA, citrate, ACD and heparine based anticoagulents). Samples containing aggregates must be clarified by centrifugation prior to testing. Suspended fibrine aggregates or particles may produce falsely positive results.

The samples should be stored at +2-8°C if the screening is carried out within 7 days or deep-frozen at -20°C. Avoid repeated freezing/thawing. If the samples are to be shipped, pack them in accordance with the regulations regarding the transport of aetiologic agents transport them preferably frozen.

DO NOT USE CONTAMINATED, HYPERLIPAEMIC OR HYPERHAEMOLYSED SERA.

REMARK : Samples containing up to 90 g/l albumin and 100 mg/l bilirubin, lipemic samples containing up to the equivalent of 36g/l triolein, and hemolyzed samples containing up to 5 g/l hemoglobin do not affect the results.

Negative and positive samples for IgM anti-HAV antibodies have been tested before and after treatment at 56°C for 30 minutes and after 3 freeze/thaw cycles. These treatments bring no impact on antibodies detection.

8 - RECONSTITUTION OF THE REAGENTS - VALIDITY - STORAGE

Before using the reagents of the Monolisa™ HAV IgM PLUS assay kit, allow them to stabilize at room temperature for 30 minutes.

1) Ready-for-use reagents

Microplate (R1)

Each frame support containing 12 strips is wrapped in a sealed bag. Cut the bag using scissors or a scalpel 0.5 to 1 cm above the sealing. Open the bag and take out the frame. Put the unused strips back into the bag. Close the bag carefully and put it back into storage at +2-8°C.

Negative Control (R3)

Positive Cut-Off (R4)

Positive Control (R5)

Sample Diluent (R6)

HAV Viral Antigen (R7a)

Conjugate (R7b)

Homogenize reagent before use.

2) Reagents to be reconstituted

Concentrated Washing solution (20X) : R2

Dilute 1:20 in distilled water to obtain the ready-for-use washing solution. Prepare 800 ml for one plate of 12 strips.

Development solution (R8 + R9)

Dilute reagent (R9) 1:11 using reagent R8 (example: 1 ml of R9 reagent in 10 ml of R8 reagent). 10 ml are necessary and sufficient for 1 to 12 strips. Homogenize.

3) Validity - Storage

The kit should be stored at +2-8°C. When stored at this temperature, each reagent contained in the kit can be used until the expiry date mentioned on the package (except for specific instructions).

R1 : After the vacuum-sealed bag has been opened, the microwell strips stored at +2-8°C in the carefully resealed bag can be used for 1 month.

R2 : The diluted washing solution can be stored at +2-30°C during 2 weeks. The concentrated washing solution (R2) can be stored at +2- 30°C.

R8 + R9 : After the reconstitution, the reagent stored in the dark can be used for 6 hours at room temperature (18-30°C).

9 - ASSAY PROCEDURE

- Strictly follow the protocol.
- Use negative and positive control sera for each test, in order to validate the test quality.
- Apply good laboratory practice.

Methods

- 1) Carefully define the sample distribution and identification plan.
- 2) Prepare the diluted washing solution (diluted R2)
- 3) Remove the microplate frame and strips (R1) from their protective bag.
- 4) Add directly and in succession, without prior washing of the microplate:
 - 80 µl of Sample diluent (R6) in each well

REMARK : It is possible to verify the presence of sample diluent in the wells by spectrophotometric reading at 620 nm (single wavelength). (Refer to section 12 : SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE AND REAGENT PIPETTING)

- 20 µl of negative control (R3) in well A1,
- 20 µl of positive Cut-Off (R4) in well B1, C1, D1,
- 20 µl of positive control (R5) in well E 1,
- 20 µl of specimen 1 in well F1,
- 20 µl of specimen 2 in well G1, etc...

Depending on the used system, it is possible to modify the position of controls or the order of distribution. Homogenise the reagent mixture. If samples distribution is over 10 mins, it is advised to distribute negative and positive controls after the samples. Incubate the Microplate immediately after distribution.

REMARK : After sample addition (or controls, or cut-off), wells containing sample diluent turn from violet to dark blue. It is possible to verify the presence of sample in the wells by spectrophotometric reading at 620 nm. (Refer to section 12 : SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE AND REAGENT PIPETTING).

- 5) When possible, cover the microplate with adhesive film. Press firmly all over the plate to ensure a tight seal.
- 6) Incubate the microplate in a thermostat-controlled water-bath or microplate incubator for 60 ± 5 minutes at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- 7) Remove the adhesive film. Aspirate the contents of all wells into a container for biohazardous waste. Add into each well a minimum of 370 μl of washing solution. Allow a soak time of at least 30 seconds. Aspirate again. Repeat this procedure a minimum of two times (i.e. in total of a minimum of 3 washes). The residual volume must be lower than 10 μl (if necessary dry the plate by turning it upside down on absorbent paper). If an automatic washer is used, follow the same procedure.
- 8) Quickly dispense 50 μl of HAV viral antigen (R7a) into all wells. The HAV viral antigen must be shaken before use.
- 9) Quickly dispense 50 μl of conjugate (R7b) into all wells. The conjugate must be shaken before use. Homogenise the reagent mixture.
REMARK : The mixture HAV viral antigen/Conjugate is coloured dark green. It is possible to verify the presence of these two reagents in the wells by two spectrophotometric reading at 450 nm and 620 nm. (Refer to section 12 : SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE AND REAGENT PIPETTING).
- 10) When possible, cover the microplate with new adhesive film and incubate for 60 ± 5 minutes at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$. Incubate the microplate in a thermostat-controlled water-bath or microplate incubator for 60 ± 5 minutes at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- 11) Remove the adhesive film, empty all wells by aspiration and wash a minimum of 4 times as described above.
- 12) Prepare development solution (R8 + R9) (Refer to section 8 : RECONSTITUTION OF THE REAGENTS).
- 13) Quickly dispense 80 μl of prepared substrate solution (R8 + R9) into all wells. Allow the reaction to develop in the dark for 30 ± 5 minutes at room temperature (18 - 30°C). Do not use adhesive film during this incubation.

REMARK : The distribution of the development solution, which is coloured pink, can be visually controlled at this step of the manipulation : there is a clear difference of colouration between an empty well and a well containing the pink substrate solution (Refer to section 12 : SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE AND REAGENTS PIPETTING).

- 14) Add 100 μl stopping solution (R10) by using the same sequence and rate of distribution as for the substrate solution.
REMARK : The distribution of the stopping solution, which is not coloured, can be visually controlled at this step of the manipulation. After the addition of the stopping solution the colour of the substrate, pink (for the negative samples) or blue (for the positive samples,) disappears for the negative samples or turns from blue to yellow for the positive samples.
- 15) Carefully wipe the plate bottom. At least 4 minutes after stopping solution addition and within 30 minutes of stopping the reaction, read the optical density at 450/620-700 nm using a plate reader.
- 16) Before recording the results, check for agreement between the reading and the microplate and sample distribution and identification plan.

10 - SYSTEM ADAPTATION

WASHING : Carefully follow the washing procedures described to obtain maximum test performance. For some systems, it may be necessary to adapt the number of wash cycles and volumes of washing solution to reach acceptable validation criteria.

11 - CALCULATION AND INTERPRETATION OF THE RESULTS

- QUALITATIVE METHOD

The presence or absence of detectable IgM anti-HAV antibodies is determined by comparing the absorbance measured for each sample to the calculated cut-off value.

1. Calculate the mean absorbance of the Positive cut-off (R4)

Example : Positive cut-off (R4)

Wells	Optical Density
B1	1.351
C1	1.402
D1	1.376
Total OD	4.129

$$\text{Mean OD R4} = \frac{\text{Total Optical Density}}{3} = \frac{4.129}{3} = 1.376$$

2. Calculation of the cut off value (CO)

$$\text{CO} = \frac{\text{Mean OD R4}}{4}$$

Example : Mean OD R4 = 1.376

$$\text{CO} = \frac{1.376}{4} = 0.344$$

3. Calculate the ratio for each sample

Sample Ratio = OD Sample / CO

4. Validation criteria are as follows

a) For negative control R3 : measured absorbance value must be less than 0.080.

b) For positive cut off R4 :

The mean measured absorbance value must be greater than 0.600 and less than 2.900.

If one of the positive cut off individual values differs by more than 30% from the mean value, disregard the value and carry out the calculation again with the two remaining positive cut off values.

c) For positive control R5 : measured absorbance value must be greater than, or equal to, CO value (Ratio ≥ 1).

The test is invalidated if the negative control R3, positive control R5 and/or more than one of positive cut off R4 are outside the interval of the above values.

5. Interpretation of the results

Samples with a ratio value less than 0.8 times the CO value (Ratio < 0.8) are considered to be negative with the Monolisa™ HAV IgM PLUS test.

Samples with a ratio value greater than, or equal to, the CO value (Ratio ≥ 1) are considered to be positive with the Monolisa™ HAV IgM PLUS test.

Samples with a ratio value greater than, or equal to, 0.8 times the CO value and less than the CO value ($1 > \text{Ratio} \geq 0.8$) must be retested in duplicate before the final interpretation.

After assay repeat, the sample is considered to be positive with the Monolisa™ HAV IgM PLUS test if the second or third measured OD value is greater than, or equal to, the CO value (Ratio ≥ 1). The sample is considered to be negative with the Monolisa™ HAV IgM PLUS test if the two measured OD values are found less than CO value (Ratio < 1).

12 - SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE AND REAGENT PIPETTING (OPTIONAL)

VERIFICATION OF SAMPLE DILUENT (R6) PIPETTING

The presence of sample diluent (R6), which is coloured violet, in the well can be verified by spectrophotometric reading at 620 nm.

The OD value of each well containing sample diluent (R6) must be greater than or equal to 0.600 and less than or equal to 1.200 ($0.600 \leq \text{OD R6} \leq 1.200$).

VERIFICATION OF SAMPLE PIPETTING

The presence of sample in the well can be verified by spectrophotometric reading at 620 nm. The OD value of each well containing diluant sample R6 and sample (or control and calibrator) must be greater than or equal to 1.250.

REMARK : After sample addition, sample diluent turns from violet to dark blue.

VERIFICATION OF HAV VIRAL ANTIGEN (R7a) AND CONJUGATE (R7b) PIPETTING

The simultaneous presence of HAV viral antigen (R7a) and conjugate (R7b) in the well can be verified by two spectrophotometric reading at 450 nm and 620 nm. The OD value of each well must be greater than or equal to 0.700 for these two reading (OD value less than 0.700 indicates a wrong distribution of HAV viral antigen or conjugate).

REMARK : HAV viral antigen (R7a) is coloured red, conjugate (R7b) is coloured blue. The mix of these two reagents give a dark green coloured solution.

VERIFICATION OF DEVELOPMENT SOLUTION (R8 + R9) PIPETTING

The presence of development solution (R8 + R9) in the well can be verified by spectrophotometric reading at 490 nm : the OD value of each well must be greater than or equal to 0.100 (a lower OD indicates a poor dispensing of the development solution).

REMARK : There is a significative colour change for the empty wells from uncoloured to pink after addition of development solution.

13 - PERFORMANCES OF THE TEST

The performance of Monolisa™ HAV IgM PLUS has been determined in 3 sites by testing samples from random blood donors, patients with acute HAV infection or showing different pathologies or status not linked to the hepatitis A , commercial panels and seroconversion panels.

A - Specificity

Specificity on 525 random blood donors was found to be 99.81% [98.94 – 100%] (IC 95), 524/525. A repeatable positive sample with Monolisa™ HAV IgM PLUS was found negative with a commercial EIA test. Furthermore, 845 patient samples (frozen or not) were tested. The specificity was found to be 99,53% [98.79%-99.87%] (IC 95), 841/845.

204 patients showing different pathologies or status not linked to the hepatitis A (pregnant women, rheumatoid factor, anti-nuclear antibodies, anti-mouse Ig or other viral or bacterial infections) have been tested with Monolisa™ HAV IgM PLUS. The specificity was found to be 99.51 % [97.30%-99.99%] (IC 95), 203/204. One IgG EBV sample was found positive with Monolisa™ HAV IgM PLUS. 9 others IgG EBV samples were found negative with Monolisa™ HAV IgM PLUS.

B - Sensitivity

Sensitivity studies were performed on 161 positive patient samples. Sensitivity was found equal to 98.14% [94.65%-99.61%] (IC 95), 158/161 after comparison with a commercial EIA test. The 3 conflicting negative samples with Monolisa™ HAV IgM PLUS concerned elderly people without acute HAV infection signs, suggesting a potential polyclonal reactivation. Two of these 3 samples were found negative with a third commercial EIA test.

17 commercial HAV seroconversion panels were also studied and compared with a commercial EIA test. The concordance between the 2 tests was found to be 100%.

C - Assay Reproducibility

The reproducibility of the Monolisa™ HAV IgM PLUS assay has been determined with the analysis of 4 samples : 1 negative sample, and 3 IgM anti-HAV Ab positive samples (low, medium, high).

The intra assay reproducibility has been evaluated by testing these 4 samples 30 times in the same run. The inter assay reproducibility has been evaluated by testing these 4 samples in duplicate during 20 days on 2 independent runs each day. Results are shown in the following tables :

Table 1 : Intra Assay Reproducibility

Sample	Negative	Low positive	Medium positive	High positive
Mean ratio	0.05	1.53	2.93	4.22
SD	0.00	0.06	0.09	0.13
CV%	5.05	4.18	3.15	3.06

Table 2 : Inter Assay Reproducibility

Sample	Negative	Low positive	Medium positive	High positive
Mean ratio	0.07	1.34	2.58	3.99
SD	0.02	0.11	0.22	0.28
CV%	22.88	8.57	8.48	7.12

14 - LIMITES OF THE TEST

Diagnosis of an infectious disease should not be established on the basis of a single test result. A precise diagnosis, in fact, should take into consideration the patient's clinical history, symptoms, as well as serological data.

Bacterial contamination of the specimens may affect the absorbance values of the samples.

15 - REFERENCES

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- (PT)** • Este medicamento contém componentes de origem humana ou animal. Manuseie com cuidado.
- (RO)** • Acest produs conține materiale de origine umană sau animală. Manevrati-l cu grijă.
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- (SK)** • Tento výrobok obsahuje ľudské alebo zvieracie zložky. Narábajte s ním opatrne.

H314 - H317

P280 - P305+P351+P338 -
P301+P330+P331 -
P303+P361+P353 -
P333+P313 - P501



(BG)

опасно

Причинава тежки изгаряния на кожата и сериозно увреждане на очите. Може да причини алергична кожна реакция.

Използвайте предпазни ръкавици/предпазно облекло/предпазни очила/предпазна маска за лице. ПРИ КОНТАКТ С ОЧИТЕ: Промийте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако има такива и доколкото това е възможно. Продължавайте да промивате. ПРИ ПОГЛЪЩАНЕ: изплакнете устата. НЕ предизвиквайте повръщане. ПРИ КОНТАКТ С КОЖАТА (или косата): Незабавно свалете цялото замърсено облекло. Облейте кожата с вода/вземете душ При поява на кожно дразнене или обрив на кожата: Потърсете медицински съвет/помощ. Извършете съдържанието/контейнера в съответствие с местните/регионалните/националните/международните разпоредби.

(CZ)

Nebezpečí

Způsobuje těžké poleptání kůže a poškození očí. Může vyvolat alergickou kožní reakci.

Používejte ochranné rukavice/ochranný oděv/ochranné brýle/obličejový štít. Při ZASAŽENÍ OČÍ: Několik minut opatrně vyplachujte vodou. Vyměňte kontaktní čočky, jsou-li nasazeny a pokud je lze vyjmout snadno. Pokračujte ve vyplachování. Při POŽITÍ: Vypláchněte ústa. NEVYVOLÁVEJTE zvracení. Při STYKU S KŮŽÍ (nebo s vlasy): Veškeré kontaminované části oděvu okamžitě svlékněte. Opláchněte kůži vodou/osprchujte. Při podráždění kůže nebo vyrážce: Vyhleďte lékařskou pomoc/ošetření. Obsah/nádobu likvidujte v souladu s místními/regionálními/národními/mezinárodními předpisy.

(DE)

Gefahr

Verursacht schwere Verätzungen der Haut und schwere Augenschäden. Kann allergische Hautreaktionen verursachen. Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen. BEI KONTAKT MIT DEN AUGEN: Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. BEI VERSCHLUCKEN: Mund ausspülen. KEIN Erbrechen herbeiführen. BEI KONTAKT MIT DER HAUT (oder dem Haar): Alle beschmutzten, getränkten Kleidungsstücke sofort ausziehen. Haut mit Wasser abwaschen/duschen. Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. Entsorgung des Inhalts / des Behälters gemäß den örtlichen / regionalen / nationalen / internationalen Vorschriften.

(DK)

Fare

Forårsager svære forbrændinger af huden og øjenskader. Kan forårsage allergisk hudreaktion.

Bær beskyttelseshandsker/beskyttelsesøj/øjenskyttelse/sigtsbeskyttelse VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning. I TILFÆLDE AF INDTAGELSE: Skyl munden. Fremkald IKKE

opkastning. VED KONTAKT MED HUDEN (eller håret): Tilmusdet vej taget straks af/fjernes. Skyl/brus huden med vand. Ved hudirritation eller udslæt: Søg lægehjælp. Bortskaffelse af indholdet/beholderen i henhold til de lokale/regionale/nationale/internationale forskrifter.

(EE)

Ettevaastus

Põhjustab rasket nahasöövitust ja silmakahjustusi. Võib põhjustada allergilist nahareaktsiooni.

Kanda kaitsekindaid/kaitseriivastust/kaitseprille/kaitsemaski. SILMA SATTUMISE KORRAL: loputada mitme minuti jooksul ettevaatlikult veega. Eemaldada kontaktläätsed, kui neid kasutatakse ja kui neid on kerge eemaldada. Loputada veel kord. ALLANEELAMISE KORRAL: loputada suud. MITTE kutsuda esile oksendamist. NAHALE (või juustele) SATTUMISE KORRAL: võtta viivitamata kõik saastunud riivad seljast. Loputada nahka veega/loputada duši all. Nahaärrituse või _obe korral: pöörelda arsti poole. Sisu/konteineri käitlus vastavuses kohalike/regionaalsete/rahvuslike/rahvusvaheliste nõuetega.

(EN)

Danger

Causes severe skin burns and eye damage. May cause an allergic skin reaction.

Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF SWALLOWED: rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention. Dispose of contents/container in accordance with local/regional/national/international regulations.

(ES)

Peligro

Provoca quemaduras graves en la piel y lesiones oculares graves. Puede provocar una reacción alérgica en la piel.

Llevar guantes que aislen del frío/gafas/máscara. EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. EN CASO DE INGESTIÓN: Enjuagarse la boca. NO provocar el vómito. EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitarse inmediatamente las prendas contaminadas. Aclararse la piel con agua o ducharse. En caso de irritación o erupción cutánea: Consultar a un médico. Eliminar el contenido o el recipiente conforme a la reglamentación local/regional/nacional/internacional.

(FI)

Vaara

Voimakkaasti ihoa syövyttävää ja silmiä vaurioittavaa. Voi aiheuttaa allergisen ihoreaktion.

Käytä suojaesineitä/suojavaatetusta/silmiensuojainta/kasvosuojainta. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Poista piilolinssit, _edical voi tehdä helposti. Jatka huuhtomista. JOS KEMIKAALIA ON NIELTY: Huuhdo suu. Ei saa oksennuttaa. JOS KEMIKAALIA JOUTUU IHOLLE (tai hiuksiin): Riisu saastunut vaatetus välittömästi. Huuhdo/suihkuta iho vedellä. Jos ilmenee ihoärsytystä tai ihottumaa: Hakeudu lääkäriin. Säilytä säiliö(t) noudattaen paikallisia/alueellisia/kansallisia/kansainvälisiä määräyksiä.

(FR)

Danger

Provoque des brûlures de la peau et des lésions oculaires graves. Peut provoquer une allergie cutanée.

Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage. EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. EN CAS D'INGESTION: rincer la bouche. NE PAS faire vomir. EN CAS DE CONTACT AVEC LA PEAU (ou les cheveux): enlever immédiatement les vêtements contaminés. Rincer la peau à l'eau/se doucher. En cas d'irritation ou d'éruption cutanée: consulter un médecin. Eliminer le contenu/réceptacle conformément à la réglementation locale/régionale/nationale/internationale.

(GR)

Κίνδυνος

Προκαλεί σοβαρά δερματικά εγκαυματα και οφθαλμικές βλάβες. Μπορεί να προκαλέσει αλλεργική δερματική αντίδραση.

Να φοράτε προστατευτικά γάντια/προστατευτικά ενδύματα/μέσα ατομικής προστασίας για ταμάτια/πρόσωπο. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΑ ΜΑΤΙΑ: Ξεπλύνετε προσεκτικά με νερό για αρκετά λεπτά. Εάν υπάρχουν φακοί επαφής, αφαιρέστε τους, εφόσον είναι εύκολο. Συνεχίστε να ξεπλένετε. ΣΕ ΠΕΡΙΠΤΩΣΗ ΚΑΤΑΠΟΣΗΣ: Ξεπλύνετε το στόμα. ΜΗΝ προκαλέσετε εμετό. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΟ ΔΕΡΜΑ (ή με τα μαλλιά): Αφαιρέστε αμέσως όλα τα μολυσμένα ενδύματα. Ξεπλύνετε το δέρμα με νερό/στο ντους. Εάν παρατηρηθεί ερεθισμός του δέρματος ή εμφανιστεί εξάνθημα: Συμβουλευθείτε/Επισκεφθείτε γιατρό. Απορρίψτε τα περιεχόμενα/δοχεία σύμφωνα με τους τοπικούς/εθνικούς/διεθνείς κανονισμούς.

(HR)

Ppasnost

Uzrokuje teške opekline kože i ozljede oka. Može izazvati alergijsku reakciju na koži.

Nositi zaštitne rukavice/zaštitnu odjelelo/zaštitu za oči/zaštitu za lice. U SLUČAJU DODIRA S OČIMA: oprezno ispirati vodom nekoliko minuta. Ukloniti kontaktne leće ukoliko ih nosite i ako se one lako uklanjaju. Nastaviti ispiranje. AKO SE PROGUTA: ispirati usta. NE izazivati povraćanje. U SLUČAJU DODIRA S KOŽOM (ili kosom): odmah ukloniti/skinuti svu zaganenu odjeću. Isprati kožu vodom/tuširanjem. U slučaju nadražaja ili osipa na koži: zatražiti savjet/pomoć liječnika. Odošite sadržaje /spremnike u skladu s lokalnim/regionalnim/nacionalni/međunarodnim odredbama.

(HU)

Veszély

Smárkiai nudegina odáj ir pažeidžia akis. Allergiás bõrreakcióit váthat ki.

Védõkesztyû/védõruha/szemvédõ/arcvédõ használatá kötelezõ. SZEMBE KERÜLÉS esetén: Több percig tartó óvatos öblítés vízzel. Adott esetben a kontaktlencsék eltávolítása, ha könnyen megoldható. Az öblítés folytatása. LENYELÉS ESETÉN: a szájat ki kell öblíteni. TILOS hánytatni. HA BÕRRE (vagy hajra) KERÜL: Az összes szennyezett ruhadarabot azonnal el kell távolítani/le kell vetni. A bõrt le kell öblíteni vízzel/zuhanyozás. Bõrirritáció vagy kiütések megjelenése esetén: orvosi ellátást kell kérni. Az edény tartalmát / a tartályt a helyi/regionális/nemzeti/nemzetközi szabályzásoknak megfelelõen kell hulladékként elhelyezni.

(IT)

Pericolo

Provoca gravi ustioni cutanee e gravi lesioni oculari. Può provocare una reazione allergica cutanea.

Indossare guanti/indumenti protettivi/Proteggere gli occhi/il viso. IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. IN CASO DI INGESTIONE: sciacquare la bocca. NON provocare il vomito. IN CASO DI CONTATTO CON LA PELLE (o con i capelli): togliersi di dosso immediatamente tutti gli indumenti contaminati. Sciacquare la pelle/fare una doccia. In caso di irritazione o eruzione della pelle: consultare un medico. Smaltire il prodotto/recipiente in conformità con le disposizioni locali / regionali / nazionali / internazionali.

(LT)

Pavojinga

Smárkiai nudegina odáj ir pažeidžia akis. Gali sukelti alerginë odos reakcijá.

Mûvéti apsaugines pirštines/dévétii apsauginius drabužius/ naudoti akių (veido) apsaugos priemones. PATEKUS Į AKIS: Kelias minutes atsargiai plauti vandeniu. Išimti kontaktinius lęsius, jeigu jie yra ir jeigu lengvai galima tai padaryti. Toliau plauti akis. PRARIJUS: išskalauti burną. NESKATINTI vémimo. PATEKUS ANT ODOS (arba plaukų): Nedelsiant nuvilkti/pašalinti visus užterštus drabužius. Odáj nuplauti vandeniu/čiurkšle. Jeigu sudirginama oda arba ją išberia: kreiptis į gydytoją. Turinį/taipá išpliti (išmesti) - šalinti pagal vietines / regionines / nacionalines / tarptautines taisykles.

(NL)

Gevaar

Veroorzaakt ernstige brandwonden en oogletsel. Kan een allergische huidreactie veroorzaken.

Beschermende handschoenen/beschermende kleding/oogbescherming/gelatsbescherming dragen. BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoelen. NA INSLIKKEN: de mond spoelen — GEEN braken opwekken. BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken — huid met water afspoelen/afdouchen. Bij huidirritatie of uitslag: een arts raadplegen. De inhoud en de verpakking verwerken volgens de plaatselijke/regionale/nationale/internationale voorschriften.

(NO)

Fare

Forårsaker alvorlige hudforbrenninger og øyeskader. Kan forårsake allergiske hudreaksjoner.

Bruk vernehansker/verneklær/vernebriller/ansiktsskjerm. VED KONTAKT MED GYNE: Skyll forsiktig med vann i opptil flere minutter. Fjern evt. kontaktlinser såfremt dette er lett mulig. Fortsett skyllingen. VED SVELGING: Skyll munnen. IKKE fremkall brekninger. VED HUDKONTAKT (eller kontakt med hår): Alle tilsolte klær må fjernes straks. Vask/dušj huden med vann. Ved hudirritasjon eller -utslett: Kontakt / tilkall lege. Innholdet / emballasjen skal avhendes i henhold til de lokale / regionale / nasjonale / internasjonale forskrifter.

(PL)

Niebezpieczeństwo

Powoduje poważne oparzenia skóry oraz uszkodzenia oczu .
Może powodować reakcję alergiczną skóry.
Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W PRZYPADKU PÓLKNIECIA: wypluć usta. NIE wywoływać wymiotów. W PRZYPADKU KONTAKTU ZE SKÓRĄ (lub z włosami): Natychmiast usunąć/zdjąć całą zanieczyszczoną odzież. Spłukać skórę pod strumieniem wody/prysznicem. W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza. Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi.

(PT)

Perigo

Provoca queimaduras na pele e lesões oculares graves. Pode provocar uma reacção alérgica cutânea.
Usar luvas de protecção/vestuário de protecção/protecção ocular/protecção facial. SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continuar a enxaguar. EM CASO DE INGESTÃO: enxaguar a boca. NÃO provocar o vômito. SE ENTRAR EM CONTACTO COM A PELE (ou o cabelo): despir/retirar imediatamente toda a roupa contaminada. Enxaguar a pele com água/tomar um duche. Em caso de irritação ou erupção cutânea: consulte um médico. Eliminar o conteúdo/recipiente de acordo com a legislação local/regional/nacional/ internacional.

(RO)

Pericol

Provoacă arsuri grave ale pielii și lezarea ochilor. Poate provoca o reacție alergică a pielii.
Purtați mănuși de protecție/îmbrăcăminte de protecție/echipament de protecție a ochilor/ chipament de protecție a feței. ÎN CAZ DE CONTACT CU OCHI: clătiți cu atenție cu apă timp de mai multe minute. Scoateți lentilele de contact, dacă este cazul și dacă acest lucru se poate face cu ușurință. Continuați să clătiți. ÎN CAZ DE ÎNGHIȚIRE: clătiți gura. NU provocați vomă. ÎN CAZ DE CONTACT CU PIELEA (sau părul): scoateți imediat toată îmbrăcăminte contaminată. Clătiți pielea cu apă/faceți duș. În caz de iritare a pielii sau de erupție cutanată: consultați medicul. Aruncați conținutul/containerul în acord cu regulamentele locale/ regionale/naționale/internaționale.

(SE)

Fara

Orsakar allvariga frätskador på hud och ögon. Kan orsaka allergisk hudreaktion.

Använd skyddshandskar/skyddskläder/ögonskydd/ansiktsskydd. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja. VID FÖRTÄRING: Skölj munnen. Framkalla INTE kräkning. VID HUDKONTAKT (även håret): Ta omedelbart av alla nedstänkta kläder. Skölj huden med vatten/duscha. Vid hudirritation eller utslag: Sök läkarhjälp. Innehållet / behållaren avfallshanteras enligt lokala / regionala / nationella / internationella föreskrifter.

(SI)

Nevarno

Povzroča hude opekline kože in poškodbe oči. Lahko povzroči alergijski odziv kože.
Nositi zaščitne rokavice/zaščitno obleko/zaščito za oči/zaščito za obraz. PRI STIKU Z OČMI: previdno izpirajte z vodo nekaj minut. Odstranite kontaktne leče, če jih imate in če to lahko storite brez težav. Nadaljujte z izpiranjem. PRI STIKU Z OČMI: previdno izpirajte z vodo nekaj minut. Odstranite kontaktne leče, če jih imate in če to lahko storite brez težav. Nadaljujte z izpiranjem. PRI STIKU S KOŽO (ali lasmi): takoj odstraniti/sleči vsa kontaminirana oblačila. Izprati kožo z vodo/prho. Če nastopi draženje kože ali se pojavi izpuščaj: poiščite zdravniško pomoč/oskrbo. Vsebinsko/vsebnik odstranite v skladu z lokalnimi/regionalnimi/narodnimi/mednarodnimi predpisi.

(SK)

Nebezpečenie

Provoca arsuri grave ale pielii și lezarea ochilor. Může vyvolat alergickou kožnú reakciu.
Noste ochranné rukavice/ochranný odev/ochranné okuliare/ochranu tváre. PO POŽITÍ: vypláchnite ústa. Nevyvolávajte zvracanie. PO POŽITÍ: vypláchnite ústa. Nevyvolávajte zvracanie. PRI KONTAKTE S POKOŽKOU (alebo vlasmi): Odstráňte/vyzlečte všetky kontaminované časti odevu. Pokožku ihneď opláchnite vodou/sprchou. Ak sa prejaví podráždenie pokožky alebo sa vytvoria vyrážky: vyhľadajte lekársku pomoc/starostlivosť. Zneškodnenie obsahu/obalu v súlade s miestnymi/oblastnými/národnými/medzinárodnými nariadeniami.

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