

NOTIS KESELAMATAN LAPANGAN **High Level Disinfectant 5L With 0.15% Peracetic Acid**

**SILA EDARKAN MAKLUMAT INI DI DALAM FASILITI ANDA KEPADA SEMUA
PENGGUNA HIGH LEVEL DISINFECTANT 5L WITH 0.15% PERACETIC ACID**

1 April 2026

Tuan/Puan yang dihargai,

**Per: High Level Disinfectant 5L With 0.15% Peracetic Acid mempunyai potensi isu
bau berlebihan, buih, kakisan dan perubahan warna**

Tujuan surat ini adalah untuk memaklumkan mengenai isu berpotensi seperti yang dinyatakan di atas yang mungkin berlaku semasa penggunaan larutan. Senarai nombor lot yang terlibat adalah seperti di bawah:

Produk	No Pendaftaran MDA	Kod Item	Nombor Lot
High Level Disinfectant 5L With 0.15% Peracetic Acid	GC7485024-157847	HLD90404	HLD404-2504 HLD404-2505 HLD404-2509

Sebab Tindakan Diambil:

Mymedic Innovation Sdn Bhd telah menerima aduan daripada Hospital Sultanah Bahiyah berkaitan potensi isu bagi produk High Level Disinfectant 5L With 0.15% Peracetic Acid seperti yang dinyatakan di atas. Ia mungkin menimbulkan risiko yang menjejaskan keselamatan pengguna dan integriti instrumen.

- Bau yang berlebihan menyebabkan iritasi dan ketidakselesaan kepada pengguna disebabkan ruang kerja yang tertutup, terutamanya semasa pengaktifan dan dalam tempoh 5 hari pertama.
- Larutan mengandungi buih yang kelihatan. Tiada sebarang potensi risiko dikenal pasti.
- Instrumen yang diperbuat daripada bahan tidak serasi dan instrumen bersalut oksida bertindak balas dengan larutan, menyebabkan kakisan dan perubahan warna.

Tindakan Diperlukan:

Pengguna dinasihatkan untuk melaksanakan tindakan berikut bagi menangani potensi isu yang berlaku:

1. Bau berlebihan

- **Memakai peralatan perlindungan diri (PPE)**

Pengguna dikehendaki memakai topeng yang sesuai, pelindung muka, sarung tangan dan apron semasa mengendalikan larutan bagi mengurangkan pendedahan kepada bau semasa pengaktifan dan penggunaan.

- **Menutup bekas rendaman**

Pastikan bekas rendaman sentiasa ditutup apabila tidak digunakan.

- **Ruang kerja dan pengudaraan**

Pengguna dinasihatkan untuk mengendalikan larutan di kawasan kerja yang mempunyai pengudaraan yang mencukupi bagi memastikan aliran udara yang baik dan mengurangkan pendedahan kepada bau, terutamanya di kawasan tertutup.

2. Buih yang kelihatan

Pengguna boleh menggunakan larutan seperti biasa mengikut Panduan Penggunaan. Tiada sebarang potensi risiko dikenal pasti kerana buih tersebut adalah normal, tidak berbahaya dan tidak menjejaskan prestasi larutan.

3. Kakisan dan perubahan warna

Jangan rendam instrumen yang diperbuat daripada bahan tidak serasi dan instrumen bersalut oksida yang terdiri daripada tembaga, loyang dan keluli tergalvani seperti instrumen *Ear Speculum* dan *Tumarkin Ear Speculum Black (coated with black oxide)*.

Langkah Diambil Untuk Menyelesaikan Isu:

- **Panduan penggunaan produk**

Pengguna dinasihatkan untuk merujuk kepada Helaiian Data Keselamatan, Panduan Penggunaan dan maklumat keselamatan yang disediakan dalam Notis Keselamatan Lapangan.

- **Semakan produk**

Mymedic Innovation Sdn Bhd telah menambah baik formulasi dengan menambah alkohol dan agen anti-kakisan bagi mengurangkan potensi risiko seperti di atas. Nombor lot pertama selepas penambahbaikan formulasi adalah HLD404-2510.



MYMEDIC INNOVATION SDN BHD 200601037776 [757536-K]

No. 8, Lorong Sukepi 1, Off Jalan Sukepi, Kawasan Perindustrian Jenjarom,
42600 Jenjarom, Selangor Darul Ehsan

+60 3 3191 4868 enquiry@mymedic.com.my

Kami menghargai kefahaman dan kerjasama anda berhubung Notis Keselamatan Lapangan ini dan memohon agar anda segera memaklumkan kepada kakitangan anda. Sila pastikan notis keselamatan ini diletakkan bersama Panduan Penggunaan sistem. Kakitangan anda perlu mengekalkan kesedaran dalam tempoh yang sesuai.

Sekiranya anda telah menjual peranti perubatan ini dan ia tidak lagi berada dalam simpanan anda, kami memohon agar notis keselamatan ini dipanjangkan kepada pemilik baharu. Sila maklumkan kepada kami mengenai pemilik baharu tersebut.

Pihak Berkuasa Peranti Perubatan akan dimaklumkan mengenai notis ini.

Yang benar,

Mohamad Farkhan Bin Damri
Pegawai
Mymedic Innovation Sdn Bhd

Pegawai yang boleh dihubungi bagi notis ini:

Jabatan : Product Compliance
Telefon : 03-3191 4868 (ext 106)
Faks : 03-3181 7868
E-mel : productcompliance@mymedic.com.my



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Pengesahan Penerimaan

Saya dengan ini mengesahkan sebagai pemilik / pengendali bertanggungjawab bagi produk *High Level Disinfectant 5L With 0.15% Peracetic Acid* untuk nombor lot HLD404-2504, HLD404-2505 and HLD404-2509 bahawa saya telah menerima dokumen berikut:

Notis Keselamatan Lapangan

High Level Disinfectant 5L With 0.15% Peracetic Acid dengan potensi isu termasuk bau berlebihan, buih, kakisan dan perubahan warna.

Tempat :
Tarikh :
Nama :

Tandatangan : _____
Cop rasmi syarikat:



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URGENT: FIELD SAFETY NOTICE
High Level Disinfectant 5L With 0.15% Peracetic Acid

PLEASE DISTRIBUTE THIS INFORMATION WITHIN YOUR FACILITY TO ALL USER OF HIGH LEVEL DISINFECTANT 5L WITH 0.15% PERACETIC ACID

April 1st 2026

Dear Sir / Madam,

Re: High Level Disinfectant 5L With 0.15% Peracetic Acid with potential issues of excessive odour, bubble, corrosion and discoloration.

The purpose of this letter is to inform you of the potential issue as stated above that may occur during solution application. The affected lot no. are listed in the table below:

Product	MDA Registration No	Item Code	Lot. No
High Level Disinfectant 5L With 0.15% Peracetic Acid	GC7485024-157847	HLD90404	HLD404-2504 HLD404-2505 HLD404-2509

Reason For The Action:

Mymedic Innovation Sdn Bhd has received complaints from Hospital Sultanah Bahiyah regarding the potential issue of High Level Disinfectant 5L With 0.15% Peracetic Acid identified above. Its may pose a risk that affects to user safety and instruments integrity.

- The odour became excessive leading to irritation and discomfort to users due to the confined workspace, particularly during activation and within the first 5 day.
- The solution contains visible bubbles. No potential risk was identified.
- Instruments made of incompatible materials and oxide coated instrument reacted with the solution, causing corrosion and discoloration.

Actions Required:

Users are advised to implement the following action to address the potential issue:

1. Excessive odour

- **Wearing personal protective equipment (PPE)**
Users are required to wear a suitable mask, face shield, glove & apron when handling the solution to minimise exposure to odour during activation and application.



- **Cover the soaking tray**
Keep the soaking tray covered when not in use.
 - **Workspace and ventilation**
Users are advised to handle the solution in a workspace with sufficient ventilation to ensure proper airflow and minimise exposure to odour, particularly in confined areas.
2. **Visible bubble**
Users can handle the solution as usual, following the instruction for use (IFU). No potential risk has been identified because that visible bubbles are a normal occurrence, harmless and do not affect the performance of the solution.
3. **Corrosion and discoloration**
Do not immerse instruments made of incompatible materials comprising copper brass and galvanized steel such as instrument Ear Speculum and Tumarkin Ear Speculum Black (coated with black oxide).

Measures Taken To Resolve The Issue:

- **Product use guidance**
Users are advised to refer Safety Data Sheet (SDS), Instruction For Use (IFU) and the safety information provided in Field Safety Notice (FSN).
- **Product review**
Mymedic Innovation Sdn Bhd has improved the formulation by adding alcohol and anti corrosion agent to mitigate the potential risk as above. Cut-off batch no is HLD404-2510.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.



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If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours

Mohamad Farkhan Bin Damri
Director
Mymedic Innovation Sdn Bhd

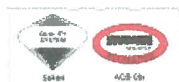
Contact person of this notification:

Department : Product Compliance

Telephone : 03-3191 4868 (ext 106)

Fax : 03-3181 7868

E-mail : productcompliance@mymedic.com.my



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Acknowledgement of receipt

I hereby confirm as the owner / responsible operator of the *High Level Disinfectant 5L With 0.15% Peracetic Acid* with the lot number HLD404-2504, HLD404-2505 and HLD404-2509 that I received the following document:

Field Safety Notice

High Level Disinfectant 5L With 0.15% Peracetic Acid with a potential issue of excessive odour, bubble, corrosion and discoloration.

Place :
Date :
Name :

Signature : _____

Company stamp:



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