



January 2023

Dear valued customer:

With this letter we are informing you of revisions to REACH (Regulation [EC] No 1907/2006 - Registration, Evaluation, Authorisation and Restriction of Chemicals) concerning substances in our products that require you, as a product user, to notify the European Chemicals Agency (ECHA) of your product use.

You'll find a list of the relevant products in Annex 1 and helpful resources for notifying ECHA of product use in Annex 2.

What has changed?

The following substances were added to REACH Annex XIV ("Authorization list"), stating they cannot be used in products without specific authorisation:

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (OPE)

4-Nonylphenol, branched and linear, ethoxylated (NPE)

These substances are used in small amounts in many in vitro diagnostic (IVD) products in the IVD industry, including in IDEXX products that you may use. See the list of affected IDEXX products in Annex I of this document.

IDEXX has received authorisation to continue use of the substances

IDEXX received authorisation from ECHA for the continued use of these substances and is actively working to phase out the use of these Authorised Substances from our products in accordance with regulatory requirements.

What does this mean for you as a customer?

Rest assured the safe, accurate, and high-quality IDEXX SNAP* tests you use have not changed, and you can continue to buy and use these products as usual in your clinic.

You are receiving this letter because REACH requires us to notify our end users of:

- + The ECHA authorisation and the presence of the Authorised Substances in the products.
- + The requirement that you must notify ECHA if you use the product(s).

This notification process is free of charge and needs to be done only once for the authorisation IDEXX received. To notify ECHA, follow the instructions found in Annex 2.

ECHA maintains a register of the user notifications and forwards the information to Member State Competent Authorities, who can confirm that all conditions of use are met. The



information collected from each notification is published in the Register of Notifications on the ECHA website. For more information, see the [ECHA website \(echa.europa.eu/support\)](https://echa.europa.eu/support).

How to find notification instructions and additional information

On the remaining pages of this document, you will find the following:

- + Annex 1. IDEXX SNAP tests containing the Authorised Substances
- + Annex 2. Instructions
 - How to notify ECHA that you use products containing Authorised Substances
 - How to access safety data sheets (SDSs) by country
 - Information for product disposal
 - Who to contact if you have questions

IDEXX is committed to providing you with the highest quality diagnostic products that meet all local safety and regulatory requirements.

Regards,

Global Product Compliance

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Annex 1. IDEXX SNAP* tests containing the Authorised Substances

You must notify ECHA if you use any of the products below.

- + You need to submit only one notification, even if you use more than one of the products.
- + You need to notify ECHA only once.

Kit part number	Kit name
99-0011514	SNAP* 4Dx* Plus Test (5)
99-26191	SNAP* 4Dx* Plus Test (5)
99-0011515	SNAP* 4Dx* Plus Test (15)
99-26192	SNAP* 4Dx* Plus Test (15)
99-0011516	SNAP* 4Dx* Plus Test (30)
99-26193	SNAP* 4Dx* Plus Test (30)
99-12024	SNAP* cPL* Test (5)
99-13419	SNAP* cPL* Test (10)
99-0001173	SNAP* Feline proBNP Test (5)
99-0001174	SNAP* Feline proBNP Test (10)
99-07895	SNAP* FeLV Antigen Test (15)
99-07896	SNAP* FeLV Antigen Test (30)
99-06033	SNAP* FIV/FeLV Combo Test (5)
99-06034	SNAP* FIV/FeLV Combo Test (15)
99-06035	SNAP* FIV/FeLV Combo Test (30)
99-11863	SNAP* Foal IgG Test (5)
99-09330	SNAP* Foal IgG Test (10)
99-26954	SNAP* fPL* Test (5)
99-14760	SNAP* fPL* Test (10)
99-10096	SNAP* <i>Giardia</i> Test (5)
99-09511	SNAP* <i>Giardia</i> Test (15)
99-09438	SNAP* Heartworm RT Test (5)
99-09439	SNAP* Heartworm RT Test (15)
99-09440	SNAP* Heartworm RT Test (30)
99-06810	SNAP* <i>Leishmania</i> Test (10)
99-07821	SNAP* <i>Leishmania</i> Test (30)
99-29849	SNAP* Lepto Test (5)
99-29301	SNAP* Lepto Test (10)
99-09214	SNAP* Parvo Test (5)



Annex 2. Instructions

How to notify ECHA that you use products containing the Authorised Substances

Detailed information can be found at the [ECHA dossier submission](https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use) web page (echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use).

Below is a summary of the notification steps.

Step 1. Have the following information ready:

- + The product authorization number: REACH/22/43/3
Note: The number is also located on the product SDS.
- + The addresses of all your company sites that use the product(s).
- + The name of a designated contact person for your company.

The following information can also be provided **but is not required**: quantity used per year and number of employees using the affected products.

Step 2. Create an ECHA account (echa.europa.eu/home) if your company does not already have one. The account gives you access to REACH-IT and to other ECHA services.

Step 3. Log in to ECHA (echa.europa.eu/home) and then follow the steps in this [video tutorial](https://www.youtube.com/watch?v=N-IGhimWBKs) ([youtube.com/watch?v=N-IGhimWBKs](https://www.youtube.com/watch?v=N-IGhimWBKs)) to submit your notification to ECHA.

How to access IDEXX safety data sheets

1. Go to the SDS page of your country's IDEXX website:

- Austria: idexx.at/de-at/about-idexx/msds/
- Czech Republic: idexx.cz/cs-cz/about-idexx/msds/
- Denmark: idexx.dk/da/about-idexx/msds/
- Finland: idexx.fi/fi/about-idexx/msds/
- France: idexx.fr/fr/about-idexx/msds/
- Germany: idexx.de/de/about-idexx/msds/
- Italy: idexx.it/it/about-idexx/msds/
- Netherlands: idexx.nl/nl/about-idexx/msds/
- Norway: idexx.no/nb/about-idexx/msds/
- Poland: idexx.pl/pl/about-idexx/msds/
- Slovakia: idexx.cz/cs-cz/about-idexx/msds/
- Spain: idexx.es/es/about-idexx/msds/
- Sweden: idexx.se/sv/about-idexx/msds/

2. On the website, click **View IDEXX SDS**.



3. Search by the **IDEXX Kit Part Number** to find all SDS documents for each of the kit components OR search by the **component part number** to find the SDS for the specific component. Do not search by product name.
4. Click the document icon .
5. Locate the document for the specific country and language, and then click **View**.

Information for the disposal of SNAP tests

- + Minimize release to the environment as far as technically and practically possible.
- + Collect all solid waste and wastewater containing the chemicals for adequate treatment.
- + Prevent release of wastewater to surface water or sewerage. Refer to the product SDS for more information. See the instructions for accessing the SDS above.

Who to contact if you have questions

If you have questions about this letter, contact Product Compliance (productcompliance@idexx.com). For other product-related questions, contact your local customer support team.