

Switching off the REACH trap

A practical guideline for moving your viral-inactivation detergent off the octylphenol-ethoxylate chemistry that is subject to REACH authorisation – six steps, a checklist, and a low-risk scale path from a 100 ml bench bottle to a 1000 L production bag.

By Sarah Gierl, Head of R&D, PAN-Celltech · TP-07 · Rev 1.0 · 20 Oct 2026 · for process development, QA and regulatory teams · companion to TP-06, [Choosing a viral-inactivation detergent](#) · [Download the PDF](#)

Key takeaways

- **This is the how, not the why.** If you have decided to move off the octylphenol-ethoxylate chemistry (subject to REACH authorisation, Annex XIV), this guideline walks the switch end to end – and a companion checklist lets your team work through it.
- **Six steps:** recover the requirement behind your spec, choose the route, trial at the bench, qualify and validate, scale up, and secure documented supply.
- **Be honest about effort.** Moving to a different chemistry (an alkyl polyglucoside, APG) is a qualified change under your quality system – not a free swap. The value is that it can be thoroughly de-risked and fully documented.
- **A low-risk scale path.** Trial a **100 ml bottle** at the bench, then a **10–20 L single-use bag** in your production environment, then scale the **identical grade** to **1000 L** – same specification and Certificate of Analysis at every rung, so scale-up is a volume change, not a product change. Bag formats are available on request.
- **What carries the switch:** [PANclear APG](#) (CT-01101) for GMP and production, [PANclear Octoxynol](#) (CT-01001) for research and analytical continuity – both manufactured to GMP on a WFI-quality water base, with a Certificate of Analysis per lot.

Deciding to switch is the easy part. This is the guideline for the week after the decision – how to move without disrupting your process or your filing.

In brief. A companion paper, TP-06, sets out why a viral-inactivation detergent now has to satisfy more than performance alone, and which chemistry fits which stage. This one assumes that decision is made and answers the next question: how do you actually carry out the switch? It gives six steps from recovering the real requirement behind an inherited specification through to secured, documented supply; a switching checklist your team can tick off; and a deliberately low-risk scale path that starts with a 100 ml bottle at the bench and

ends at a 1000 L production bag using the identical grade throughout. Two honest threads run through it: a change of chemistry is a qualified change under your quality system and is treated as one, and the practical job of a supplier is to take as much risk and documentation off your plate as possible.

The switch, in six steps

1 Recover the requirement behind the spec

Start by writing down what the step actually has to achieve, independent of the product currently named in the SOP: reliable inactivation of enveloped viruses by lysis of the lipid envelope, under your real conditions, with defined clearance and material compatibility downstream. An inherited specification often records a product name and nothing about the requirement behind it; recovering that requirement is what makes everything after this step a matching exercise rather than a guess. [TP-06](#) sets out the full requirement list and a decision checklist to do this cleanly.

2 Choose the route

Two routes, chosen by where you sit. For GMP and production and for new processes, move to a **different chemistry** – an alkyl polyglucoside (APG), which is not an octylphenol ethoxylate and therefore not subject to REACH authorisation (Annex XIV), and can be supplied at production scale. Where a validated research method or analytical procedure still calls for the octylphenol-ethoxylate chemistry, keep it for research and analytical use. A common pattern is to use the APG route for production and retain the octylphenol-ethoxylate grade only where a research or analytical method requires it.

3 Trial at the bench

Before any commitment, run the candidate in your own process at small scale. A [100 ml bottle of PANclear APG](#) is available for bench trials, so testing can start without a project set-up. Confirm performance on your own material, at your own concentration, time and temperature, and check handling and compatibility. This is a low-cost, low-commitment gate: it tells you whether to proceed before you open formal change control.

4 Qualify and validate

Because this is a change of chemistry, it is handled as a **qualified change under your pharmaceutical quality system** – not an informal substitution. In practice that means opening change control with a risk assessment (in the spirit of [ICH Q9\(R1\)](#)), and qualifying the new detergent against the viral-safety expectations

that apply to your process, including viral-clearance and inactivation performance consistent with [ICH Q5A\(R2\)](#). Typical elements: confirm inactivation performance at your set point; confirm downstream **clearance** of the detergent; check **material compatibility** with product, resins and membranes; and record it all under [ICH Q10](#). The guideline does not remove this work – it structures it, and the bench trial in step 3 means you enter it with first data on your own material.

5 Scale up – one grade, three rungs

Scale on a single grade so that nothing about the material changes as the volume grows. The same PANclear APG you qualified at the bench is the material you receive at production scale, with the same specification and Certificate of Analysis at every step.

RUNG 1 · BENCH

100 ml bottle

Bench trial

Confirm performance on your own material and conditions, with minimal commitment.

RUNG 2 · PRODUCTION ENVIRONMENT

10–20 L bag

Single-use, on request

The same grade in a small single-use bag, to test in your actual production setting – fluid path, mixing, hold – before full scale.

RUNG 3 · PRODUCTION

up to 1000 L bag

Full scale, on request

The identical grade and specification at full scale. A volume change, not a product change.

Formats: 100 ml bottles; 500 ml and 1000 ml bottles, single-use bags from 10–20 L up to 1000 L and custom fills on request. The grade, specification and Certificate of Analysis are the same on every rung.

6 Document and secure supply

Close the switch by locking in the paperwork and the supply. Each lot is released with a **Certificate of Analysis**; both grades are manufactured by PAN-Celltech to GMP in an EU Annex 1 facility (a capability, not a certification) within an ISO 9001 quality system, on a WFI-quality water base. Update your specifications, SOPs and the article number to the new grade, so the inherited product name does not linger in your documents. If your project needs larger volumes of the octylphenol-ethoxylate grade or a use beyond research and analysis, talk to us early – every enquiry is reviewed against the intended use and the applicable REACH requirements.

The switching checklist

A single page your process, QA and regulatory leads can work through together. It mirrors the six steps and turns them into things you can tick off.

Replacing an octylphenol-ethoxylate viral-inactivation detergent

- ✓ **Requirement recovered.** The function and acceptance criteria the step must meet are written down – not just the old product name.
- ✓ **Route chosen.** APG for GMP and production; the octylphenol-ethoxylate grade retained only where a research or analytical method requires it.
- ✓ **Bench trial done.** 100 ml tested in your own process; performance confirmed on your own material and conditions.
- ✓ **Change control opened.** Risk assessment started under your quality system (ICH Q9(R1) / Q10).
- ✓ **Viral performance qualified.** Inactivation and clearance confirmed consistent with ICH Q5A(R2) for your process.
- ✓ **Compatibility checked.** Material compatibility with product, resins and membranes, and downstream detergent clearance, verified.
- ✓ **Production-environment test done.** 10–20 L single-use bag run in your real setting.
- ✓ **Documentation in hand.** Certificate of Analysis per lot, GMP statement and the regulatory documentation your QA requires.
- ✓ **Supply secured.** Target scale and formats agreed with the supplier, up to 1000 L.
- ✓ **Records updated.** Specifications, SOPs and article number changed to the new grade.

Common pitfalls

What slows a switch down

- **Specifying by brand name again.** Writing another product name into the SOP repeats the original issue. Specify by chemistry and requirement instead.
- **Treating a chemistry change casually.** It is a qualified change; plan the change control and the viral-performance work from the start rather than discovering it late.

- **Skipping the production–environment rung.** Jumping from a 100 ml bench bottle straight to full scale skips the 10–20 L bag test that catches fluid–path and handling surprises cheaply.
- **Leaving the REACH question to the end.** Check early which of your uses of the octylphenol–ethoxylate chemistry are covered: use in scientific research and development, including routine analysis, under controlled conditions and below 1 tonne per year is exempt; other uses require an authorisation.
- **Letting the old name linger.** Specs, SOPs and labels that still carry the inherited product name undo the switch on paper. Update the records.

Said plainly

A switching guideline should not pretend the work away. Moving to a new chemistry is a real change that you qualify and document under your own quality system, and this paper is written to make that path shorter and surer, not to skip it. What a good supplier can genuinely remove is risk and paperwork: material to start testing quickly, one grade that does not change as you scale from bottle to bag, and a Certificate of Analysis on every lot. The honest boundary: the REACH status noted here is stated for the chemistry class as a factual compliance note, not legal or regulatory advice, and the obligations for a given use, format and territory are confirmed per order.

Frequently asked questions

Including the questions customers most often ask us by brand name.

We specified "Triton™ X-100" in our SOP – where do we start? —

Start at step 1: write down the requirement behind the name – reliable inactivation of enveloped viruses under your conditions, with defined clearance and compatibility – independent of the product currently specified. "Triton™ X-100" is a brand of The Dow Chemical Company for an octylphenol ethoxylate (ingredient name octoxynol-9); once the requirement is written down, you choose a chemistry against it rather than re-specifying a brand.

What is the REACH status of octylphenol ethoxylates such as Triton™ X-100?

Octylphenol ethoxylates degrade to an endocrine-disrupting octylphenol, so they are on the REACH Authorisation List (Annex XIV). Since the 2021 sunset date, their use in the EU requires an authorisation; use in scientific research and development, including routine analysis, carried out under controlled conditions and below 1 tonne per year, is exempt (Art. 3(23) and Art. 56(3) REACH). This applies to the chemistry class under any of the substance's names. PANclear APG is an alkyl polyglucoside, a different chemistry, and is not subject to it.

Is moving to PANclear APG a simple substitution?

No – and it is important to say so. Because APG is a different chemistry, moving to it is a qualified change handled under your quality system, with a risk assessment and viral-performance qualification consistent with ICH Q5A(R2). What PAN removes is the risk and the lead time around that work: trial a 100 ml bottle in your own process, then scale the identical grade through a 10–20 L production-environment bag to 1000 L, with the same specification and Certificate of Analysis at every step.

Can we start testing quickly?

Yes. The 100 ml bottle of PANclear APG is available for bench trials, so testing can start without a project set-up. The same grade then scales to a 10–20 L single-use bag for production-environment testing and up to 1000 L for production, with bag formats available on request.

Can we keep the octylphenol-ethoxylate chemistry (Triton™ X-100 / octoxynol) for an existing method?

Yes. PANclear Octoxynol keeps the octylphenol-ethoxylate chemistry available in GMP quality, supplied for research and analytical use in 100 ml bottles. Larger volumes and custom formats are available on request; every enquiry is reviewed against the intended use and the applicable REACH requirements.

Do you use genuine Triton™ raw material?

Yes. Both PANclear grades are formulated by PAN-Celltech from genuine Triton-branded raw material – Triton™ X-100 for PANclear Octoxynol and Triton™ CG-110 (an alkyl polyglucoside) for PANclear APG – for applications in which octylphenol ethoxylates such as Triton™ X-100 have so far been used. PANclear is PAN's own brand; Triton is a trademark of The Dow Chemical Company and PAN is not affiliated with or endorsed by Dow.

Start your switch with a bench bottle

Tell us which viral-inactivation step you run and at what scale. We will supply a 100 ml PANclear APG bottle for your bench trial, and map the scale path and documentation around your process.

info@pan-celltech.com

Triton™ is a trademark of The Dow Chemical Company. PANclear products are PAN-Celltech's own brand, formulated from genuine Triton-branded raw material; PAN is not affiliated with, sponsored by, or endorsed by Dow. Triton is named here only as the raw material used and in the factual REACH context.

Related: [TP-06 Choosing a viral-inactivation detergent](#)

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Manufactured to GMP in an EU Annex 1 facility within an ISO 9001 quality system (a capability, not a certification). References to ICH Q5A(R2), Q9(R1) and Q10 describe the customer's own frameworks and are context, not regulatory advice. REACH status is stated for the chemistry class as a factual compliance note; obligations for a given use, format and territory are confirmed per order. TP-07.