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REPLY FROM THE EUROPEAN UNION TO THE COMMENTS RECEIVED FROM THE AUSTRALIAN GOVERNMENT REGARDING NOTIFICATION

G/TBT/N/EU/1172

DRAFT COMMISSION DELEGATED REGULATION AMENDING REGULATION (EC) NO1272/2008 AS REGARDS THE HARMONISED CLASSIFICATION AND LABELLING OF CERTAIN SUBSTANCES

The European Union would like to thank the Australian Government for providing comments on the draft "Commission Delegated Regulation (EU) amending regulation No 1272/2008 as regards the harmonised classification and labelling of certain substances."

The EU would like to provide the following reply to these comments.

Tea tree oil

The Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP regulation) sets the rules for hazard classification and labelling of hazardous substances. The CLP regulation implements the Globally Harmonized System for Classification and Labelling (GHS) at European level. Like GHS, the CLP regulation and the classification process it sets out are purely hazard based.

The classification of tea tree oil as presumed toxicant to human reproduction (category 1B Fertility), among other hazard classes, is based on the scientific opinion of the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA), based on a comprehensive evaluation of available data using a weight-of-evidence approach according to the criteria laid down in the CLP regulation and GHS.

The Commission has discussed the RAC's scientific opinion with Member States and representative stakeholders in the Competent Authorities for REACH and CLP (CARACAL) expert group, with a view to decide on the harmonised classification of tea tree oil in the CLP regulation.

Representatives of concerned European industries, as well as other interested parties, were invited to be part of this discussion. This rigorous and transparent process aimed at ensuring that the classification of tea tree oil relies on the most scientifically sound and solid information.

The draft regulation was notified by the European Commission, in accordance with the WTO TBT rules, providing the opportunity to comment in a period of 60 days from notification.

The EU would like to note that the draft 24th amendment of the CLP regulation was presented for a final consultation at the CARACAL meeting on 28 January 2026.

Based on that consultation, as well as on all previously received comments, including TBT comments, the EU concluded that the proposed classification of tea tree oil is appropriate and is currently in the process of adopting the Commission Delegated Regulation. The CARACAL agreed to restrict the scope of the entry to tea tree essential oil only, compared to all extracts from tea tree as proposed in the RAC opinion.

Under the CLP regulation, the harmonised classification will trigger labelling and packaging obligations. There is a transitional period before a harmonised classification becomes applicable, the usual duration of which is to be counted as follows: the first day of the month following 18 months after the day of entry into force - the date of entry into force being usually 20 days after publication in the Official Journal of the European Union.

Whether and to what extent harmonised classification will have consequences under other EU legislation will depend on the conditions of that legislation.

As regards specific comments:

- *Appropriateness of rat -to-human extrapolation and limitations in the scientific evidence*

Comments regarding the appropriateness of rat-to-human extrapolation and applicability of studies dosed by gavage were raised by industry stakeholders during the public consultation leading to the adoption of the RAC opinion.

In its opinion, RAC has considered such studies as relevant for hazard classification, as this is consistent with the OECD Test Guidelines under which these studies were conducted.

The relevant section at pages 26-27 of the RAC opinion addresses these comments:

> *'While RAC considers that the available data is supportive of the classification for Reproductive toxicity in category 1B; H360F, it has also considered whether there are any reasons that would support a different outcome:*
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> *− The DS and stakeholders expressed some doubt on human relevance, taking into account that such effects were not reported in humans exposed to components of TTO at relatively high doses with food. However, DS and RAC note that no human data on TTO are available.*
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> *− In addition, RAC received comments regarding a hypothesis to explain the mode-of-action (MoA) for the spermatogenesis via a metabolite of p-cymene. This*

metabolite was shown to have a clear quantitative species differences in accumulation between rats and humans in vitro. RAC responded regarding the proposed MoA via a p-cymene metabolite, that the clearance of the p-cymene metabolite in human hepatocytes might be higher compared to rat hepatocytes, still the overall metabolisation in vivo is not known for this component, let alone that (quantitative) differences in metabolisation are known for the full TTO 27 mixture (p-cymene presents in the range of 0.5-8 %). Therefore, it is not possible to either exclude another MoA nor conclusively demonstrate the human non-relevance.

− Concerning the comment relating to the applicability of studies dosed by gavage, RAC considers such studies as relevant for hazard classification (as also noted in the STOT RE section), as this is consistent with the OECD TG under which these studies were conducted.'

- *Diverse determinations on the safety of tea tree oil in the EU*

As regards the Scientific Committtee for Consumer Safety (SCCS) Opinion on Tea Tree Oil as an ingredient in cosmetic products (SCCS/1681/25), it should be noted that the SCCS performs a safety assessment that is based on both hazard and risk assessment. The SCCS concluded on tea tree oil safety under certain conditions.

However, additional criteria must be met for a CMR category 1 substance to be allowed in cosmetic products, beyond a confirmed safe use. These include, inter alia, that the substance complies with food safety requirements, that no suitable alternatives are available, and that the specific uses are justified. Any derogation would therefore require a dedicated regulatory assessment and decision-making process in accordance with Article 15(2) of Regulation (EC) No 1223/2009.

The Commission will assess the implications for cosmetics once the classification under the CLP regulation is finalised, taking due account of the SCCS opinion and in accordance with the legal requirements laid down in the Cosmetics Regulation.

As regards the substance's existing regulatory status in other EU frameworks, it should be noted that the classification process under the CLP regulation is purely hazard-based. Other pieces of EU legislation cover risk assessment and management where necessary.

<u>Lithium carbonate, chloride, and hydroxide (lithium salts)</u>

The classification of lithium carbonate, lithium chloride and lithium hydroxide as known toxicants to human reproduction with regard to the effects on the foetal development (category 1A Development) and presumed toxicants to human reproduction with regard to effects on male fertility (category 1B Fertility) was proposed based on a comprehensive evaluation of available data, including animal

studies and evidence from human exposure, using a weight-of-evidence approach according to the criteria laid down in the CLP regulation and GHS.

The first Opinion from the Risk Assessment Committee of ECHA (RAC) published in 2021 suggested classifying the three lithium salts as reprotoxicants for development (category 1A) and for fertility (category 1B), based on the CLP criteria, which stem from GHS.

A second RAC opinion, published in 2024, considered an additional epidemiological study unknown at the time of the first opinion in 2021 and confirmed the conclusions of the first opinion.

The CLP regulation, as GHS does, calls for a comprehensive analysis of all available data. It does not require any generation of data. Where the criteria cannot be applied directly to available identified information, a weight of evidence determination shall be applied.

This is why RAC took into account, using a weight-of-evidence approach, all available data including epidemiological studies, animal studies performed according to OECD Test Guidelines and animal studies not conducted according to internationally validated guidelines.

The CLP regulation and its harmonised classification focus only on hazardous properties of substances. Other pieces of legislation cover risk assessment and management where necessary.

The Commission has discussed the RAC's scientific opinions with Member States and representative stakeholders in the Competent Authorities for REACH and CLP (CARACAL) expert group, with a view to decide on the harmonised classification of these three lithium salts in the CLP regulation.

Representatives of concerned European industries, as well as of other interested parties, were invited to be part of this discussion. A series of CARACAL discussions was held in 2025.

This rigorous and transparent process aims at ensuring that the classification of these salts rely on the most scientifically sound and solid information.

The draft regulation was notified by the European Commission, in accordance with the WTO TBT rules, providing the opportunity to comment in a period of 60 days from notification. Comments received from the Government of Australia were shared with the CARACAL expert group.

The EU would like to note that the draft 24th amendment of the CLP regulation was presented for a final consultation at the meeting of Competent Authorities on CARACAL meeting on 28 January 2026.

Based on that consultation, as well as on all previously received comments, including TBT comments, the EU concluded that the proposed classification of the substances

lithium salts is appropriate and is currently in the process of adopting the Commission Delegated Regulation.

Under the CLP regulation, the harmonised classification will trigger labelling and packaging obligations. There is a transitional period before a harmonised classification becomes applicable.

The usual duration of the transition is to be counted as follows: the first day of the month following 18 months after the day of entry into force - the date of entry into force being usually 20 days after publication in the Official Journal of the European Union. Whether and to what extent harmonised classification will have consequences under other EU legislation will depend on the conditions of that legislation.

The hazardous properties of these substances will trigger the need for industry, or competent authorities, to perform a risk assessment in order to determine whether and which risk management measures should be implemented to ensure production and use of these substances for lithium-based technologies which would be safe for both human health and the environment.

Possible indirect consequences would be limited to operations in the EU, with possible adaptations of industrial processes, e.g., to ensure occupational safety of workers. We understand that many companies in the lithium supply chain currently operate with existing risk mitigation measures in place to ensure a sound occupational safety for their workers. Hence, current risk mitigation measures already in place may suffice. This would especially be the case when such companies handle other hazardous chemicals, which have equivalent harmonised classifications as the three lithium salts.

The Commission fully acknowledges the critical importance of lithium salts as key enablers for the climate, green and energy transitions.

The European Commission stands by its strong commitment to the successful development of a responsible and sustainable lithium supply chain. The Commission is confident that this classification will not endanger the endeavour to secure a reliable value chain related to lithium that is economically, socially, and environmentally sustainable for the European Union, as well as for Australia.

The EU would like to thank the Australian Government once again for providing comments on the notified draft and hopes that the responses conveyed sufficiently clarify the issues raised.

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Electronically signed on 03/07/2026 17:04 (UTC+02) in accordance with Article 11 of Commission Decision (EU) 2021/2121