Agency Opinion on the classification and labelling of

1-ethoxy-2-(2-methoxyethoxy)ethane

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Agency Opinion

The aim of the Agency Opinion is to formally propose the GB mandatory classification and labelling (GB MCL) for **1-ethoxy-2-(2-methoxyethoxy)ethane**, based on the scientific and technical assessment of the scientific data in line with the GB Classification, Labelling and Packaging Regulation ('the GB CLP Regulation') together with an assessment of the policy and socio-economic impacts on the UK.

Executive summary

1-ethoxy-2-(2-methoxyethoxy)ethane is an industrial chemical that falls within the scope of the UK REACH Regulation and has an entry on the 'UK REACH: grandfathered registrations notified substance list' (July 2021). It is manufactured and/or imported into the European Economic Area, at volumes of ≥ 1 000 to < 10 000 tonnes per annum (ECHA, 2026).

1-ethoxy-2-(2-methoxyethoxy)ethane has no existing mandatory classification and labelling entry in the GB MCL list.

In accordance with Article 37 of the 'assimilated Regulation (EC) No. 1272/2008 as amended for Great Britain' (the GB CLP Regulation), it is the Opinion of HSE (as the GB CLP Agency) that the proposed classification and labelling for **1-ethoxy-2-(2-methoxyethoxy)ethane** is:

- Repr. 1B; H360FD (May damage fertility. May damage the unborn child)

This is in agreement with the conclusions of the Agency Technical Report on 1-ethoxy-2-(2-methoxyethoxy)ethane.

The justification for proposing this new GB MCL for 1-ethoxy-2-(2-methoxyethoxy)ethane is based on the scientific and technical assessment of the available data (based on the Agency Technical Report for 1-ethoxy-2-(2-methoxyethoxy)ethane) which supports the proposed GB MCL.

No significant direct policy or socio-economic impacts are expected, as identified by the Impact and Policy Assessment.

Article 37A consideration

This Agency Opinion was drafted in accordance with Article 37 of the GB CLP Regulation. The Opinion on 1-ethoxy-2-(2-methoxyethoxy)ethane adopted by the European Chemicals Agency (ECHA) Committee for Risk Assessment (RAC) (i.e., the RAC Opinion) was used as the basis for the Agency Technical Report, which in turn is the basis for the proposed GB MCL proposed in this Agency Opinion.

According to the GB CLP Regulation, HSE (as the GB CLP Agency) has the option of proposing its own new or revised mandatory classification and labelling under Article 37A, where it is considered that the evidence in the RAC Opinion does not support the classification outcome.

In the case of 1-ethoxy-2-(2-methoxyethoxy)ethane, the Agency Opinion does not differ from the RAC Opinion, so further assessment under Article 37A is not required.

Scientific and technical assessment

Introduction

The scientific and technical assessment of 1-ethoxy-2-(2-methoxyethoxy)ethane was conducted by HSE specialists in line with the criteria set out in the GB CLP Regulation and is reported in full in the Agency Technical Report for 1-ethoxy-2-(2-methoxyethoxy)ethane. Information supporting the classification of 1-ethoxy-2-(2-methoxyethoxy)ethane in the Agency Technical Report is based on the RAC Opinion, as stipulated under Article 37 of the GB CLP Regulation. Only those hazard classes that were open for consideration in the RAC Opinion are considered in the Agency Technical Report.

Summary of the Agency Technical Report

A summary of the hazard classes assessed as part of this Opinion is provided below:

- **Physical hazard classes:** no physical hazard classes were assessed in the Agency Technical Report. This is in agreement with the RAC Opinion.
- **Health hazard classes:** hazard classes covering reproductive toxicity were assessed in the Agency Technical Report. This is in agreement with the RAC Opinion.
- **Environmental hazard classes:** no environmental hazard classes were assessed in the Agency Technical Report. This is in agreement with the RAC Opinion.

The Agency Technical Report agrees with the classification proposed by RAC for the following hazards:

- Repr. 1B; H360FD (May damage fertility. May damage the unborn child)

Overall, the conclusion is to agree with the RAC Opinion.

Additional information

No additional information was considered for the proposed GB MCL for 1-ethoxy-2-(2-methoxyethoxy)ethane.

Impact and Policy Assessment

Introduction

The aim of the Impact and Policy Assessment (IPA) is to summarise the direct impacts of the proposed GB MCL for 1-ethoxy-2-(2-methoxyethoxy)ethane and associated socio-economic costs and benefits, identified from a range of activities. This includes considering available information from government surveys and interested stakeholders, such as UK government departments with associated regulatory responsibilities, the Devolved Governments where they have devolved responsibilities and wider national and international stakeholders where appropriate.

A formal regulatory impact assessment in line with HM Treasury's Green Book is not required for non-legislative routine scientific and technical changes such as new/revised mandatory classification and labelling. Instead, HSE adopts a proportionate approach to estimating impacts in order that UK Government is informed and prepared for any anticipated direct impacts of the mandatory classification changes.

Use profile

1-ethoxy-2-(2-methoxyethoxy)ethane falls within the scope of the UK REACH Regulation, and there is an entry for this substance in the 'UK REACH grandfathered registrations notified substances list'.

1-ethoxy-2-(2-methoxyethoxy)ethane is used in the formulation of printer ink, toners and other paper and board treatment products (CLH, 2024).

Regulatory impact of the proposed GB MCL

The proposed mandatory classification and labelling may trigger restrictions under the UK REACH Regulation.

In the UK, the proposal to classify 1-ethoxy-2-(2-methoxyethoxy)ethane as Repr. 1B; H360FD (May damage fertility. May damage the unborn child) has the potential to trigger further control measures under UK REACH Annex 17 restrictions whereby the substance could be restricted from being placed on the market for public use. The proposed GB MCL of the substance also meets the criteria to be considered under Article 57 of UK REACH for the identification of substances of very high concern (SVHC) which could lead to authorised use of the substance in the UK.

Under downstream national legislation, the classification of 1-ethoxy-2-(2-methoxyethoxy)ethane means that under the Control of Substances Hazardous to Health Regulations (COSHH), the principles of good practice will apply, and a workplace risk assessment will need to be completed that may lead to additional costs.

No concerns have been raised in respect of the proposed GB MCL by Scottish or Welsh Devolved Governments, Northern Ireland (NI) government departments, UK government bodies or national and international stakeholders. On this basis, it is

concluded that the proposed GB MCL for 1-ethoxy-2-(2-methoxyethoxy)ethane will have no significant regulatory impact.

Socio-economic impact estimate

Societal impact

No direct beneficial or detrimental impacts as a result of the proposed GB MCL for 1-ethoxy-2-(2-methoxyethoxy)ethane were reported by the Scottish or Welsh Devolved Governments, NI government departments, UK government bodies, or national/international stakeholders.

Owing to the proposed GB MCL,1-ethoxy-2-(2-methoxyethoxy)ethane could potentially be subject to further control measures under the UK REACH Regulation. There is no indication from the UK REACH Work Programme that 1-ethoxy-2-(2-methoxyethoxy)ethane is being considered for inclusion in the UK REACH Candidate list or in the UK REACH Authorisation list for Substances of Very High Concern. However, this does not preclude future consideration of control measures for 1-ethoxy-2-(2-methoxyethoxy)ethane under the UK REACH Regulation.

Cost

Previous assessment of the associated direct costs of revised classification of chemical substances by HSE identified that the revision of the classification is likely to result in costs associated with familiarisation and relabelling during manufacturing and supply of related products. Costs associated with impacts under downstream legislation are considered indirect and are not considered a consequence under CLP.

The classification and labelling system of chemicals is established in the UK. The chemical industry is familiar with mandatory classifications. Checking a mandatory classification is likely to take only a few minutes. Similarly, familiarisation costs for employees are expected to be negligible, as the system of warning phrases and pictograms is provided on labels. We therefore estimate that the costs of familiarisation are negligible.

For chemical substances, the cost of relabelling[1], has been estimated as between £155 to £505. Given that labels are frequently changed for marketing purposes (about every 18 months for some sectors), and companies have a transitional period of approximately 18 months in which to change their labels in order to comply with the mandatory classification, it is estimated that, the majority of duty holders should be able to achieve compliance without incurring any additional costs of updating labels as a result of mandatory classification.

In addition, the UK REACH Regulation requires that a Safety Data Sheet (SDS) is produced for active substances and mixtures containing the active substances and

[1] Average relabelling costs based on 2021 values are estimated to fall within the range of £155-£505 per substance per company. These costs are based on an assessment of the impact of changes affecting Poison Centres produced by the Department of Health, in conjunction with HSE in July 2016. These estimates were updated values based on costs used in the short impact assessment for the 1st ATP to CLP conducted in 2008, and the impact estimate for the 3rd ATP conducted in 2012, where costs were estimated to lie between £150 and £500.

the SDS may need to be updated. These costs are not expected to be significant, given the routine and expected nature of updates and the relatively low estimated cost per update.

Benefit
Mandatory classifications result in a reduced cost to business where, in the past, they have had to undertake self-classification for the substances in question and is potentially a significant benefit to industry.

There are additional benefits from the mandatory classification such as establishing a level playing field between GB-based businesses and their competitors and increasing certainty and clarity around the classification and labelling of substances and packaging, which increases reassurance for duty holders, consumers and regulators**.**

Wider considerations

Environmental Principles Statement
Section 17(5) of The Environment Act 2021 introduced five principles that need to be given due regard when considering new policies. HSE, as the CLP Agency, has considered the impact that the GB MCL will have on the five principles (integration, prevention, rectification, polluter pays and precautionary) and has not identified positive or negative environmental impacts, as the GB CLP Regulation is a non-permissioning Regulation. Environmental impacts are considered in other direct permissioning Regulations such as the GB Plant Protection Products Regulation, the GB Biocide Products Regulation and UK REACH.

National impacts
No wider government policy issues or concerns have been raised by the Scottish or Welsh Devolved Governments, NI government departments, UK government bodies or national/international stakeholders that would require GB mandatory classification and labelling to be implemented in a different way. As a result, mitigation measures are not warranted.

EU/Northern Ireland
The proposed GB MCL for 1-ethoxy-2-(2-methoxyethoxy)ethane is the same as the harmonised classification proposed in the RAC Opinion and therefore with the classification in the EU (and NI). Therefore, the proposed GB MCL for 1-ethoxy-2-(2-methoxyethoxy)ethane will have no significant effects on existing NI and GB supply chains, as classification in NI and GB will be the same.

International impacts
No wider issues have been raised at this stage of the GB MCL procedure.

Overall IPA conclusion

The only clear direct policy and socio-economic impacts identified from this IPA are the direct costs linked to changes in mandatory classification, such as familiarisation and relabelling of chemical products. Duty holders responsible for the classification and labelling of products containing 1-ethoxy-2-(2-methoxyethoxy)ethane have not

previously commented or raised specific concerns with HSE as the Agency on the direct costs of these changes, therefore we have assumed that these costs are covered by HSE's generic costing for related costs such as relabelling and familiarisation for professional use associated with new/revised GB MCLs.

There is potential for 1-ethoxy-2-(2-methoxyethoxy)ethane to be identified as a SVHC and to be subject to control measures under the UK REACH Regulation.