Brussels, 13 July 2022

Subject: EIGA comment on the Proposed harmonised classification for Dinitrogen oxide
EC / List no: 233-032-0
CAS no: 10024-97-2

EIGA welcomes the opportunity to comment on the proposed harmonised classification for dinitrogen oxide.

The proposed harmonised classification on health effects is different from the classification used by our members. As required by REACH, dinitrogen oxide was registered by our members. A Chemical Safety Report and a classification were made at that time following a robust assessment of the available studies. The EIGA members have monitored the evolution of data published with respect to health and environmental inpact with a view to reconsider the classification. It is our opinion that no research has been published that would change the classification of N2O.

ERM, a consultancy firm sponsored by Kayser, reviewed in detail the literature study and annex mentioned on the webpage 'Registry of CLH intentions until outcome – dinitrogen oxide'. Report No : 0649151-Tox 1 from 7 july 2022 : "Proposal for Harmonised Classification and Labelling of Dinitrogen oxide : Position paper discussing reproductive and developmental CLH proposals." We have read this review via one of our members. EIGA will not copy the exact report with its comments but wishes to emphasize that our members support the comments contained within the report from ERM.

The literature regarding ozone depletion is also not new. The literature was considered by the registrants at the time of registration. The experts concluded the data to be conclusive but not sufficient for classification.

EIGA's members are concerned about the misuse of dinitrogen oxide as a drug and its effects on human health when used inappropriately. This is an unintended use of dinitrogen oxide. One of the correct and intended uses is its application in equipment for food and this has nothing to do with the possible effects of inhalation.
It is EIGA's opinion that trying to prevent any misuse by changing the classification is not the proper route to effect change. This should be controlled via REACH or other legislation related to the use.

About the European Industrial Gases Association (EIGA)
EIGA – is a safety and technically oriented organisation representing the vast majority of European and also non-European companies producing and distributing industrial, medical and food gases. The member companies closely co-operate in technical and safety matters to achieve the highest level of safety and environmental care in the handling of gases. EIGA is in frequent touch with Standardisation and Regulatory Organisations and Authorities as well as trade and industrial organisations. EIGA's membership comprises European companies that produce or distribute industrial and/or medical gases. As such, EIGA itself does not produce or market industrial or medical gases.