AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

GLUTARAL

AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of
Regulation (EC) 1907/2006[1]

Adopted on 3 June 2021

This agreement concerns

Substance name: Glutaral

EC number: 203-856-5

CAS number: 111-30-8

Molecular formula: C5H8O2

Structural formula:

[1]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Sweden presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (2 March 2021) on identification of *Glutaral (EC No. 203-856-5)* as a substance of very high concern due to its respiratory sensitising properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.

The Annex XV dossier was circulated to Member States on 10 March 2021 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 24 May 2021 and agreed in the written procedure of the Member State Committee with closing date of 3 June 2021.

Agreement of the Member State Committee in accordance with Article 59(8):

Glutaral **is identified as a substance meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because it is a substance with respiratory sensitising properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.**

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

Respiratory sensitising properties - Article 57(f):

Glutaral is identified as a substance of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) because it is a substance with respiratory sensitising properties for which there is scientific evidence of probable serious effects to human health which gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of the REACH regulation.

Sensitisation is an irreversible malfunction of the immune system which leads to a permanently increased risk of serious adverse health effects. There are numerous studies on workers who became sensitised to glutaral and developed occupational asthma (**OA**). Asthma is a serious health effect that may result in permanent impairment of lung function. It has been reported that ex-employees with previous glutaral exposure have significantly lower lung function than current employees. Asthma may also have fatal effects.

Most studies on the effects of glutaral describe both an early onset (type I) and a late phase (delayed) asthmatic response. Several studies report an increase of IgE antibodies specific to glutaral both in humans and in mice after inhalation exposure to glutaral.

Symptoms of respiratory tract sensitivity have been shown to arise after variable periods of workplace exposure. Studies report symptoms appearing from 3 months up to 23 years from the first exposure to glutaral. In addition, the typical non-specific symptoms of glutaral associated asthma (chest tightness, persistent cough, and wheezing) have been coupled with a delay in symptoms after exposure and may lead to a delayed diagnosis. If the symptoms cannot be immediately coupled to the exposure, there is a risk that exposure will continue and that the asthma will be further aggravated, leading to irreparable damage to lung function.

In addition to its respiratory sensitising properties, glutaral is a strong skin sensitiser with a harmonised classification as Skin Sens. category 1A. It has been indicated that skin exposure and skin sensitisation to glutaral may be of importance for respiratory sensitisation.

Long-term illness, such as asthma or impairment of lung function as a result thereof, limits the possibility of living a normal working and private life. Asthma may indeed require long-term medication. Sensitised individuals may need to change workplace and profession and retraining of affected staff may be required.

Several studies have investigated the cost implications of respiratory sensitisation for society in terms of e.g., healthcare, retraining, production losses (due to e.g., sick leave and reduced work capability) and impaired quality of life. There are also data on the economic or societal costs attributed to glutaral induced OA that demonstrate large costs for the society.

There is currently no established method to determine a safe concentration for respiratory hypersensitivity, or data suitable to define such thresholds for glutaral. The difficulty to derive a safe exposure level is illustrated by (i) well-documented reports on cases of OA caused by glutaral where allergic reactions in the airways have been reported at low exposure levels and (ii) variable national and international occupational exposure limits primarily based on respiratory effects.

Considering the type and severity of the health effects mentioned above, the delay and irreversibility of such effects, their impacts on the person's quality of life and the overall societal concern and costs, glutaral can be regarded as giving rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of the REACH regulation.

Therefore, it is concluded that the substance g*lutaral* meets the criteria of Article 57(f) of REACH, due to its respiratory sensitising properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those for other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.

Reference:

Support Document (Member State Committee, 3 June 2021)