



Notes on the use of formalin, reclassified as “carcinogenic”

SIAPEC-IAP Italian Division guidelines (February, 2016)

Note: this is an internal translation work; for the original document, see “Note relative all’utilizzo della formalina, ri-classificata cancerogena”. Such document was released by the Italian Society of Anatomical Pathology and diagnostic Cytopathology – Italian Division of I.A.P. (International Academy of Patology).

Introduction

In accordance with the EU Regulation n. 895/2014, formaldehyde has been reclassified as carcinogenic (category 1B) and mutagenic (category 2). According to the new classification, operational since 1st April 2015, then extended to 1st January 2016, both European and Italian regulations require to consider the carcinogenic risk, in order to safeguard the health and safety of operators who are exposed to formaldehyde (Legislative Decree n. 81, 9th April 2008, protection against carcinogenic and mutagenic agents). This reclassification, according to the CLP (classification, labelling and packaging) regulation concerning the carcinogenic agents that belong to category 1B, assigns the risk phrases H350 and H350i (according to the Legislative Decree 52/1997, they were classified as cat. 2 carcinogenic agents, risk phrases R45 and R49). For this reason, within the work environments where formalin is used and is potentially inhaled by operators, it is necessary to update the Risk Assessment Document (within 30 days since 1st January) in compliance with the instructions of Title IX of the Legislative Decree 81/08 (protection against carcinogenic and mutagenic agents) and to enforce all the expected obligations (specific professional training, removal or reduction of the risk by adopting closed systems, use of adequate protection devices - both individual and collective, sanitary surveillance put in place by the competent doctor).

Taking into consideration the significant and widespread use of formaldehyde in the Anatomic Pathology service, the SIAPEC-IAP Italian Division has considered it appropriate to define some guidelines concerning the adjustment of prevention and protection measures to implement starting from the first half of 2016.

State of the art

On an international level, formalin is used to fix tissues and is considered the best and ideal fixative for a number of reasons:

- It is readily available;
- It is cheap;
- It keeps the cellular morphology and the tissue structure intact;
- It cannot be altered (if kept at a normal temperature, away from direct sunlight);
- Currently, nothing similar or potentially replaceable can be found on the market;
- All the protocols related to histochemical, immunohistochemical and molecular investigations, including the analyses on neoplastic pathology with prognostic and predictive purposes, are currently standardised on formalin-fixed tissues;
- The data on the scientific literature concerning the carcinogenic risk for exposure to formaldehyde within the Anatomic Pathology services are scarce and inconclusive.



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