Histo-Line Laboratories

**IVD** dispositivo medico-diagnostico in vitro CE

# Data sheet Prefilled container SafeSystem with 10% neutral buffered formalin

| **CE IVD** | *In vitro diagnostic medical device* | Supplier*: Histo-Line Laboratories Srl* |
|---|---|---|

| ***Code*** | ***Product*** | ***Volume*** | ***Packaging*** |
|---|---|---|---|
| 07-124-02-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 20 ml | 224 pz (screw cap) |
| 07-124-03-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 30 ml | 150 pz (screw cap) |
| 07-124-04-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 40 ml | 150 pz (screw cap) |
| 07-124-06-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 60 ml | 90 pz (screw cap) |
| 07-124-08-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 80 ml | 90 pz (screw cap) |
| 07-124-09-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 90 ml | 90 pz (screw cap) |
| 07-124-12-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 120 ml | 50 pz (screw cap) |
| 07-124-25-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 250 ml | 120 pz (screw cap) |
| 07-124-05-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 500 ml | 60 pz (screw cap) |
| 07-124-01-S | Prefilled container SafeSystem with 10% neutral buffered formalin | 1000 ml | 22 pz (screw cap) |
| | | | |

CND code W01030705

Stability of products properly conserved at 15-25°C 24 months.

Product description
The rule CEE/UE 05/06/2014 n° 605 and CEE/UE 23/03/2015 n° 491 modified the previous indication and from 1st January 2016 formaldehyde is considered CARC 1B H350, in order to avoid gas exit from prefilled container DDKItalia develop a system "controlled vapor release see additional info below" a polymer film is added on top of prefilled container this avoid gas exit, also as requested by Padova University (I), all cap are transparent, technicians can control tissue without opening container. Do not agitate prior use, in case wait until film get stabilized.

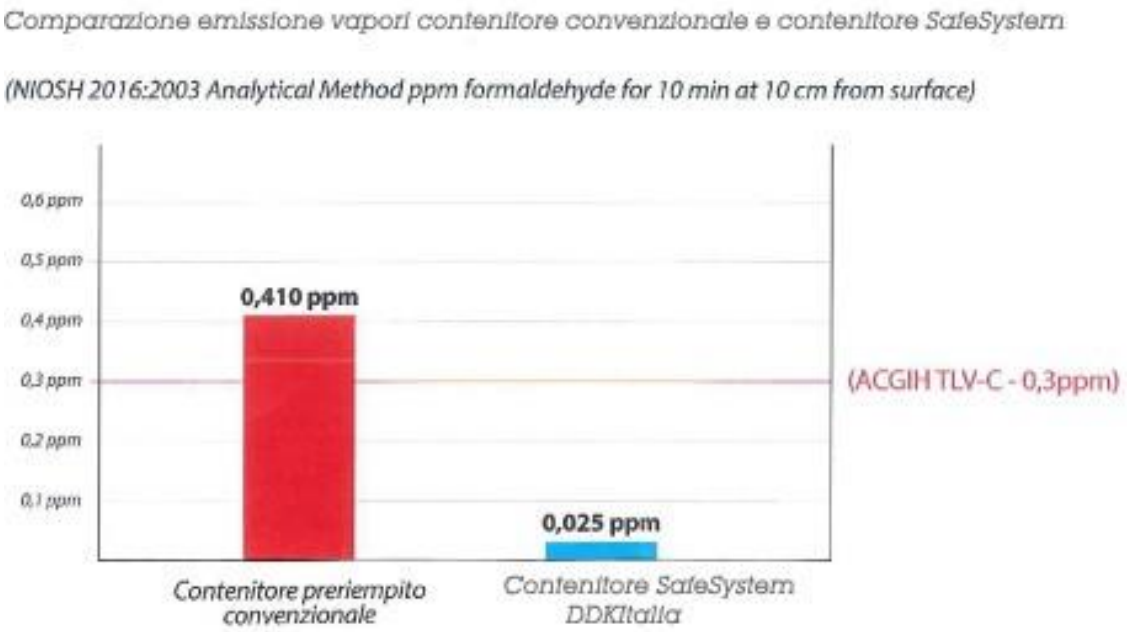
Soon after an organism dies, or a tissue is removed from the body, putrefaction and autolysis begin. Autolysis is retarded by cold, greatly accelerated at temperature of about 30°C, and almost inhibited by heating to 50°C.
There are very few instances when specimens are examined without fixation or some form of hardening. The aim of fixation is to stop decay, putrefaction and autolysis. Proper tissue fixation is essential for accurate histopathologic evaluation. If properly preserved, the cell and tissue constituents should appear in as lifelike a manner as possible. In reality each fixative creates a unique set of artefacts'. The living cell is fluid, or in a semi-fluid state. Formaldehyde is both a noncoagulant and an additive fixative. Formalin fixation is thought to form cross links between the aldehydes and the proteins, creating a gel, thus retaining cellular constituents in their in vivo relationship. Once properly fixed, the tissue should be able to withstand the subsequent stages of tissue processing or staining.

Procedure
Fixation should begin as soon as possible.
Be sure the tissue is placed in the proper fixative. If the tissue cannot be immediately placed into the fixative, keep the tissue moist and cool.
Typically the tissue is kept moist with normal saline or isotonic PBS.
The ideal ratio of fixative to tissue should be in the range of 20 to 50 parts of fixative to 1 part tissue.
The ratio of fixative to tissue should never be less than 10 to 20 parts of fixative to 1 part tissue.
Tissue intended for museum preparation should be placed in a ratio of 100 parts fixative to 1 part tissue and the ratio should never be less than 50 parts fixative to 1 part tissue.
Whole organs should be injected with fixative as well as immersed in fixative. Large organs can be sliced to allow better penetration of the fixative into the tissue.
Hollow organs can be injected with fixative or can be packed with absorbent cotton soaked in fixative before immersion. Some organs such as colon may be opened and pinned to a corkboard before immersion into the fixative. The time needed for fixation can range from just a few hours to several weeks.
The time needed will vary upon the tissue type and the size or thickness of the specimen.
After fixation has been completed, the fixed tissue should be trimmed to no more than 3 to 5 mm in thickness and placed on a tissue processor for paraffin processing.
The first alcohol the tissue contacts should be 70%.

Placing formalin fixed tissues into high percentage alcohols can result in the precipitation of the phosphate buffered salts used to prepare the formalin.

Precautions
This product is for R&D use only, not for drug, household, or other uses. Please consult the Material Safety Data Sheet for information regarding hazards and safe handling practices.
If shipping tissue fixed in formalin, comply with all state, local or federal laws.
If cells and cellular structures are not properly preserved and stabilized by fixation, any testing performed on the tissue will be of mediocre or possibly unusable quality. Misdiagnosis may result if the tissue is improperly handled or fixed.
The end user must determine the proper fixative and the conditions necessary for proper fixation. If the ratio of fixative to tissue is not adequate, tissue may deteriorate or putrefy during long-term storage.
There are tissues and constituents which are not properly preserved by formalin.

Storage - stability
Store tightly closed at room temperature. Do not freeze. The expiration dating is printed on the product label.
Preparation Instructions. Ready to use. Dilution may be required for certain specialized applications, or for concentrated solution.




References
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Theory and Practice of Histotechnology, 2nd Edition. Dezna C. Sheehan and Barbara B Hrapchak. Battelle Press, Columbus, 1980.
An Introduction to Histotechnology, Geoffrey G. Brown, Appleton-Century-Crofts, New York, 1978.
Humason's Animal Tissue Techniques, 5th Edition, Edited by Janice K. Presnell and Martin R. Schreibman, The John Hopkins University Press, Baltimore 1997. Theory and Practice of Histological Techniques, Edited by John D Bancroft and Marilyn Gamble, Churchill Livingstone, London, 2002.

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CE

| Misure contenitori – Container size | | |
|---|---|---|
| | | |
| | With out cap mm | With cap mm |
| | Senza tappo mm | Con tappo mm |
| | | |
| 20 ml | | |
| | H 43,0 | H 44,0 |
| | R 31,0 | R 36,0 |
| | | |
| 30/40 ml | | |
| | H 40,0 | H 41,0 |
| | R 44,0 | R 49,0 |
| | | |
| 60 ml | | |
| | H 59,0 | H 60,0 |
| | R 44,0 | R 49,0 |
| | | |
| 80/90 ml | | |
| | H 74,0 | H 75,0 |
| | R 44,0 | R 49,0 |
| | | |
| 120/150 ml | | |
| | H 78,0 | H 79,0 |
| | R 52,0 | R 53,0 |
| | | |
| 160 ml | H 85,0 | H 86,0 |
| | R 52,0 | R 53,0 |
| | | |
| 500 ml | | |
| | H 110,00 | H 111,00 |
| | R 89,0 | H 98,0 |
| | | |
| 1000 ml | | |
| | H 139,00 | H 141,00 |
| | R 111,00 | R 122,00 |

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