

MATERIAL SAFETY DATA SHEET

1. Product and company identification

Product: Product No: Tumor Marker Control 108-20

Manufacturer: Fujirebio Diagnostics AB Elof Lindälvs gata 13 SE-414 58 Göteborg, Sweden www.fdi.com, info@fdab.com



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2. Hazards Identification

Classification: None of the kit components of the Tumor Marker Control kit may be classified as hazardous due to the low concentration of hazardous ingredients.

Both Tumor Marker Control Level 1 and Tumor Marker Control Level 2 contain human serum and must be handled as a potentially infectious substance following Universal Precautions requirements in OSHA Standard 1910.1030, Bloodborne Pathogens.

Symbol according to EN 980:2008, Biological risks.



Special hazards: Contains human sourced and/or potentially infectious components.

3. Composition / Information on Ingredients

The components of this kit are mixtures. Minimal objective scientific information is available on the hazards of this mixture, and as a consequence it is assumed to have the same hazards as the chemical ingredient parts when present in certain concentrations. These chemical ingredients are listed below if they: (1) are defined as hazardous and are present in concentrations of 1% or greater (0.1% or greater if e.g. carcinogenic, mutagenic or very poisonous) or (2) present a physical hazard in the mixture.

Tumor Marker Control Level 1: Human serum Tumor Marker Control Level 2: Human serum

None of the kit components of the Tumor Marker Control contain chemical substances listed in PRTR regulation.

Additional information: Contains human sourced and/or potentially infectious components.

4. First aid measures

Inhalation: Remove victim from source of exposure. If breathing is difficult, administer oxygen.

Skin exposure: In case of contact, wash with plenty of soap and water. Seek medical attention if irritation develops.

Eyes: Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes. Seek immediate medical attention.

Ingestion: Give 2-3 glasses of water to drink and do not induce vomiting. Seek immediate medical attention.

5. Fire-fighting measures

Use extinguishing media appropriate to surrounding materials. No special equipment or procedures are required.

6. Accidental release measures

Absorb spills of reagents and patient samples with absorbent paper, taking care not to spread the material. Clean spill area with a freshly made 0.5 % sodium hypochlorite (bleach) solution. Discard all materials used to absorb spill and disinfect area into biohazard waste collection for proper disposal. Avoid contact with eyes and skin.

7. Handling and storage

Handling: Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette patient samples or reagents by mouth. Avoid splashing or aerosol formation. Use all reagents in accordance with the relevant package insert. Avoid high temperatures during transport.

Storage: Store all reagents as directed in the relevant package insert.

8. Exposure controls / personal protection

Engineering controls: None required

Follow universal precautions. Wear appropriate personal protective equipment when working with reagents or patient specimens, including lab coats, disposable gloves and eye protection. Avoid hand/mouth contact.

Wash hands as soon as possible after handling reagents or patient specimens.

9. Physical and chemical properties

Physical state of the Tumor Marker Control: cream colored, odorless, solid, lyophilized material.

10. Stability and reactivity

The Tumor Marker Control components are stable under the storage conditions described in the package insert. Hazardous decomposition will not occur. There are no known strong incompatibilities.

11. Toxicological information

The components of this kit are mixtures. Toxicological studies have not been performed on this mixture. Based on the composition of the components, these materials are believed to be non-toxic.

12. Ecological information

The components of this kit are mixtures. Ecological studies have not been performed on this mixture. Based on the composition of the components, these materials are not believed to be an ecological hazard.

13. Disposal considerations

Dispose as an infectious waste in accordance with all federal, state and local regulations.

14. Transport information

No limitations apply

15. Regulatory information

This product is classified and labelled in accordance with EEC directives directive 2001/58/EC and 99/45/EC as modified by1907/2006 and 453/2010.

U.S Regulations: This product is evaluated in accordance with 29 CFR 1910.1200.

Canadian Regulations: This product has been classified according to the hazard criteria of the Canadian regulation, the Controlled Products Regulations, and the MSDS contains all the information required by the Controlled Products Regulations.

This product is also classified and labeled in accordance with the Japanese regulation PRTR.

16. Other information

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End of Safety Data Sheet