EU REACH Substance Communication – Invasive Cardiology

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GE Healthcare works with its suppliers to ensure compliance of articles imported or manufactured within the European Union that are subject to the REACH regulation (EC- No 1907/2006), Article 33, and used in the production of GE Healthcare products.

Regarding the application of Article 33 of the REACH regulation and the publication of the Candidate List of Substances of Very High Concern (SVHC) according to Article 59 of REACH regulation, GE Healthcare is aware of its legal obligations and will comply with them.

GE Healthcare articles do not "intentionally release" substances under normal conditions of use.

Based on information from our suppliers to date, these substances are present in the following products at a concentration that may be greater than the threshold of 0.1% (w/w) at the article level:

|  |  |  |
| --- | --- | --- |
| **Product Name** | **Substance name** | **CAS Number** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
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| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare travaille avec ses fournisseurs pour assurer la conformité des articles importés ou fabriqués dans l'Union européenne qui sont soumis au règlement REACH (CE-No 1907/2006), Article 33, et utilisés dans la production de ses produits.

En ce qui concerne l'application de l'article 33 du règlement REACH et la publication de la liste des substances extrêmement préoccupantes (SVHC) conformément à l'article 59 du règlement REACH, GE Healthcare est consciente de ses obligations légales et s'y conformera.

Les articles GE Healthcare ne libèrent pas intentionnellement des substances dans des conditions normales d'utilisation.

Selon les informations dont disposent nos fournisseurs à ce jour, ces substances sont présentes dans les produits suivants à une concentration qui pourrait être supérieure au seuil de 0,1% masse à masse au niveau de l’article :

|  |  |  |
| --- | --- | --- |
| **Nom du produit** | **Nom de la substance** | **n° CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
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| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
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| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
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GE Healthcare работи със своите доставчици, за да осигури съответствие на артикулите, внесени или произведени в рамките на Европейския съюз, които са в обхвата на Регламента REACH (ЕО – № 1907/2006), член 33, и които се използват в производството на продуктите на GE Healthcare.

По отношение на прилагането на член 33 на Регламента REACH и публикуването на списъка с предложения за пораждащи сериозно безпокойство вещества (SVHC) съгласно член 59 на Регламента REACH GE Healthcare е осведомена относно своите правни задължения и ще ги спази.

Артикулите на GE Healthcare не „отделят умишлено“ вещества при нормални условия на употреба.

Въз основа на информация от нашите доставчици към днешна дата тези вещества са налични в следните продукти при концентрация, която може да е по-голяма от прага от 0,1% обемни процента, при ниво на артикул:

|  |  |  |
| --- | --- | --- |
| **Име на продукт** | **Наименование на веществото** | **CAS №** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
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| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
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| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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Společnost GE Healthcare spolupracuje se svými dodavateli na zajištění souladu výrobků dovážených nebo vyrobených v Evropské unii, které podléhají směrnici REACH (EC- č. 1907/2006), článek 33, a použitých při výrobě produktů GE Healthcare.

Pokud jde o aplikaci článku 33 nařízení REACH a publikaci Candidate List of Substances of Very High Concern (SVHC) (Seznam navržených látek vzbuzujících mimořádné obavy) podle článku 59 směrnice REACH, společnost GE Healthcare si je vědoma zákonných závazků a bude je dodržovat.

Výrobky společnosti GE Healthcare za normálních podmínek „záměrně neuvolňují“ tyto látky.

Na základě informací od našich dodavatelů k dnešnímu dni jsou tyto látky v následujících produktech obsaženy v koncentraci, která může být vyšší než prahová hodnota 0,1 % (hmotnostního poměru) na úrovni jednotlivého produktu:

|  |  |  |
| --- | --- | --- |
| **Název produktu** | **Název látky** | **Č. CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
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GE Healthcare trabaja con sus proveedores para garantizar el cumplimiento del reglamento REACH (CE n.º 1907/2006), artículo 33, en artículos importados o fabricados dentro de la Unión Europea sujetos a dicho reglamento y que se utilicen en la producción de productos de GE Healthcare.

En relación con la aplicación del artículo 33 del reglamento REACH y la publicación de la lista de sustancias candidatas extremadamente preocupantes (SEP) de acuerdo con el artículo 59 del reglamento REACH, GE Healthcare está al tanto de sus obligaciones legales y las cumple.

Los artículos de GE Healthcare no "liberan intencionalmente" sustancias en condiciones normales de uso.

Sobre la base de la información de nuestros proveedores hasta la fecha, estas sustancias están presentes en los siguientes productos con una concentración que puede ser mayor que el umbral del 0,1 % (w/w) en peso a nivel del artículo:

|  |  |  |
| --- | --- | --- |
| **Nombre del producto** | **Nombre de la sustancia** | **número CAS.** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare samarbejder med sine leverandører for at sikre overensstemmelse af artikler, der er importeret eller fremstillet inden for EU, som er underlagt REACH-forordningen (EF nr. 1907/2006), artikel 33, og som anvendes i produktionen af GE Healthcare-produkter.

Med hensyn til anvendelsen af artikel 33 i REACH-forordningen og offentliggørelsen af kandidatlisten over særligt farlige stoffer (SVHC) i henhold til artikel 59 i REACH-forordningen er GE Healthcare bekendt med sine juridiske forpligtelser og vil overholde dem.

GE Healthcare-artikler "frigiver ikke tilsigtet" stoffer under normale brugsforhold.

På baggrund af oplysninger fra vores leverandører til dato findes disse stoffer i følgende produkter ved en koncentration, der kan være større end grænseværdien på 0,1 vægtprocent på artikelniveau:

|  |  |  |
| --- | --- | --- |
| **Produktnavn** | **Stofnavn** | **CAS-nr.** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare arbeitet mit seinen Lieferanten zusammen, um die Konformität von Artikeln sicherzustellen, die in die Europäische Union eingeführt oder dort hergestellt werden, die der REACH-Verordnung (EG-Nr. 1907/2006), Artikel 33, unterliegen und die bei der Herstellung von GE Healthcare-Produkten verwendet werden.

Hinsichtlich der Anwendung von Artikel 33 der REACH-Verordnung und der Veröffentlichung der Kandidatenliste für besonders besorgniserregende Stoffe (SVHC-Liste) gemäß Artikel 59 der REACH-Verordnung ist GE Healthcare sich seiner rechtlichen Verpflichtungen bewusst und wird diese einhalten.

Artikel von GE Healthcare geben unter normalen Nutzungsbedingungen keine Stoffe „absichtlich frei“.

Basierend auf Informationen unserer jetzigen Lieferanten sind diese Stoffe in den folgenden Produkten mit einer Konzentration vorhanden, die höher sein kann als der Schwellenwert von 0,1 % des Artikelgewichts:

|  |  |  |
| --- | --- | --- |
| **Produktname** | **Stoffname** | **CAS-Nr.** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare teeb oma tarnijatega koostööd, et tagada nende Euroopa Liidus imporditud või toodetud toodete vastavus, millele kohaldub REACH-määruse ((EÜ) nr 1907/2006) artikkel 33 ning mida kasutatakse GE Healthcare'i toodete tootmisel.

Seoses REACH-määruse artikli 33 kohaldamise ja väga ohtlike ainete kandidaatainete nimekirja (SVHC) avaldamisega REACH-määruse artikli 59 kohaselt on GE Healthcare oma juriidilistest kohustustest teadlik ning täidab neid.

GE Healthcare'i toodetest ei ole tavalistes kasutustingimustes ainete „eraldumine ette nähtud“.

Tarnijatelt saadud teabe kohaselt on need ained järgmistes toodetes olemas sisalduses, mis võib toote tasemel olla suurem kui piirväärtus 0,1 massiprotsenti:

|  |  |  |
| --- | --- | --- |
| **Toote nimetus** | **Aine nimetus** | **CASi nr** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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Η GE Healthcare συνεργάζεται με τους προμηθευτές της για τη διασφάλιση της συμμόρφωσης των αντικειμένων που εισάγονται ή κατασκευάζονται εντός της Ευρωπαϊκής Ένωσης, υπόκεινται στον κανονισμό REACH (ΕΚ- Αρ. 1907/2006), Άρθρο 33 και χρησιμοποιούνται για την παραγωγή των προϊόντων της GE Healthcare.

Αναφορικά με την εφαρμογή του Άρθρου 33 του κανονισμού REACH και τη δημοσίευση του Καταλόγου υποψήφιων ουσιών που προκαλούν πολύ μεγάλη ανησυχία (Candidate List of Substances of Very High Concern, SVHC) σύμφωνα με το Άρθρο 59 του κανονισμού REACH, η GE Healthcare έχει λάβει γνώση των νομίμων υποχρεώσεών της και θα συμμορφώνεται με αυτές.

Τα αντικείμενα της GE Healthcare δεν "απελευθερώνουν εκουσίως" ουσίες υπό κανονικές συνθήκες χρήσης.

Βάσει πληροφοριών από τους προμηθευτές μας έως σήμερα, αυτές οι ουσίες υπάρχουν στα παρακάτω προϊόντα σε ποσοστό συγκέντρωσης που ενδέχεται να είναι μεγαλύτερο από το όριο του 0,1% βάρος προς βάρος σε επίπεδο αντικειμένου:

|  |  |  |
| --- | --- | --- |
| **Όνομα προϊόντος** | **Ονομασία ουσίας** | **Αριθμός CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare surađuje s dobavljačima kako bi osigurao sukladnost proizvoda uvezenih ili proizvedenih u Europskoj uniji koji su podložni uredbi REACH (EZ – br. 1907/2006), Članak 33, a koriste se u proizvodnji proizvoda tvrtke GE Healthcare.

Vezano uz primjenu Članka 33 uredbe REACH i objave Popisa predloženih posebno zabrinjavajućih tvari za odobrenje (SVHC) sukladno Članku 59 uredbe REACH, GE Healthcare je upoznat sa svojim pravnim obavezama i ispoštovat će ih.

Proizvodi tvrtke GE Healthcare prilikom uobičajene uporabe tvari ne „ispuštaju namjerno“.

Sukladno informacijama dobivenim od naših dobavljača do današnjeg datuma, ove su tvari prisutne u sljedećim proizvodima u koncentraciji koja može biti veća od granične vrijednosti 0,1 % (w/w) na razini artikla:

|  |  |  |
| --- | --- | --- |
| **Naziv proizvoda** | **Naziv tvari** | **CAS broj** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare collabora con i suoi fornitori per garantire la conformità degli articoli importati o prodotti nell'Unione Europea soggetti al regolamento REACH (CE N. 1907/2006), articolo 33, e utilizzati nella fabbricazione di prodotti GE Healthcare.

Per quanto riguarda l'applicazione dell'articolo 33 del regolamento REACH e la pubblicazione dell'elenco delle sostanze candidate estremamente preoccupanti (SVHC, Substances of Very High Concern) in conformità all'articolo 59 del regolamento REACH, GE Healthcare è a conoscenza dei suoi obblighi legali e si impegna a rispettarli.

Gli articoli GE Healthcare non "rilasciano intenzionalmente" sostanze in condizioni di normale utilizzo.

In base alle informazioni aggiornate ad oggi ottenute dai nostri fornitori, queste sostanze sono presenti nei seguenti prodotti in una concentrazione che potrebbe essere superiore alla soglia dello 0,1% in peso/peso a livello di articolo:

|  |  |  |
| --- | --- | --- |
| **Nome prodotto** | **Denominazione della sostanza** | **N. CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare sadarbojas ar saviem piegādātājiem, lai nodrošinātu atbilstību Eiropas Savienībā importētajām vai ražotajām precēm, uz kurām attiecas REACH regulas (EK Nr. 1907/2006) 33. pants un kas tiek izmantotas GE Healthcare produktu ražošanā.

Attiecībā uz REACH regulas 33. panta pielietojumu un kandidātvielu, kas rada ļoti lielas bažas (SVHC), publikāciju saskaņā ar REACH regulas 59. pantu GE Healthcare apzinās savas likumīgās saistības un tās ievēros.

GE Healthcare preces normālos lietošanas apstākļos “tīši neizdala” vielas.

Pamatojoties uz mūsu piegādātāju sniegto informāciju, šīs vielas turpmāk minētajos produktos ir koncentrācijā, kas var pārsniegt 0,1 % svara robežvērtību pēc svara preces līmenī:

|  |  |  |
| --- | --- | --- |
| **Izstrādājuma nosaukums** | **Viela** | **CAS Nr.** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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„GE Healthcare“ bendradarbiauja su savo tiekėjais, kad užtikrintų, jog prekės, importuotos arba pagamintos Europos Sąjungoje, atitiktų REACH reglamento (EB Nr. 1907/2006) 33 str. nuostatas, ir yra naudojamos „GE Healthcare“ produktų gamybai.

„GE Healthcare“ supranta savo teisinius įsipareigojimus pagal REACH direktyvos 33 str. ir Labai didelį susirūpinimą keliančių medžiagų kandidatų sąrašą pagal REACH direktyvos 59 str., ir jų laikosi

„GE Healthcare“ produktai įprastomis naudojimo sąlygomis „sąmoningai neišskiria“ medžiagų į orą.

Remiantis mūsų tiekėjų turima informacija, šios medžiagos toliau išvardintuose produktuose gali būti didesnės koncentracijos nei ribinė 0,1 % svorio pagal svorį koncentracija prekės lygiu:

|  |  |  |
| --- | --- | --- |
| **Gaminio pavadinimas** | **Cheminės medžiagos pavadinimas** | **CAS Nr.** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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A GE Healthcare együttműködik a beszállítókkal annak biztosítása érdekében, hogy az Európai Unióban gyártott, az Európai Unióba importált, illetve a GE Healthcare termékek előállítása során felhasznált árucikkek megfeleljenek a REACH szabályozás (EK 1907/2006) 33-as cikkelyének.

A GE Healthcare tisztában van jogi kötelezettségeivel, és eleget tesz a REACH szabályozás 33-as cikkelye és 59-es cikkelye (különös aggodalomra okot adó anyagok (SVHC) jelöltlistájának publikálása) által előírtaknak.

A GE Healthcare árucikkek normál felhasználási körülmények között szándékosan nem bocsátanak ki anyagot.

Az eddigi beszállítóink információi alapján ezek az anyagok olyan koncentrációban vannak jelen a következő termékekben, amely lehet, hogy nagyobb a 0,1% (w/w) tartománynál a termék szintjén:

|  |  |  |
| --- | --- | --- |
| **Termék neve** | **Anyag neve** | **CAS-szám.** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare taħdem mal-fornituri tagħha biex tiżgura konformità mal-oġġetti importati jew manifatturati fl-Unjoni Ewropea li huma soġġetti għall-Artikolu 33 tar-Regolament REACH (KE- Nru 1907/2006), u jintużaw fil-produzzjoni tal-prodotti ta’ GE Healthcare.

Fir-rigward tal-applikazzjoni tal-Artikolu 33 tar-Regolament REACH u l-pubblikazzjoni tal-Lista ta’ Kandidati ta’ Sustanzi ta’ Tħassib Serju Ħafna (SVHC) skont l-Artikolu 59 tar-Regolament REACH, GE Healthcare hija konxja dwar l-obbligi legali tagħha u se tikkonforma magħhom.

L-oġġetti ta’ GE Healthcare ma “jirrilaxxawx intenzjonalment” sustanzi f’kundizzjonijiet normali ta’ użu.

Abbażi tal-informazzjoni mill-fornituri tagħna sa issa, dawn is-sustanzi huma preżenti fil-prodotti li ġejjin f’konċentrazzjoni li tista’ tkun akbar mil-limitu ta’ 0.1 % piż b’piż fil-livell tal-oġġett:

|  |  |  |
| --- | --- | --- |
| **Isem il-prodott** | **Isem tas-sustanza** | **Nru CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare werkt samen met zijn leveranciers om ervoor te zorgen dat artikelen die zijn geïmporteerd of geproduceerd binnen de Europese Unie voldoen aan de REACH-verordening (EG-nr. 1907/2006) artikel 33 en worden gebruikt bij de productie van GE Healthcare-producten.

GE Healthcare is op de hoogte van zijn wettelijke verplichtingen omtrent de toepassing van artikel 33 van de REACH-verordening en de publicatie van de Kandidaatslijst van zeer zorgwekkende stoffen volgens artikel 59 van de REACH-verordening, en zal deze naleven.

Onder normale omstandigheden geven de artikelen van GE Healthcare niet 'opzettelijk' stoffen af.

Op basis van de huidige informatie van onze leveranciers zijn deze stoffen aanwezig in de volgende producten met een concentratie die mogelijk hoger is dan de drempel van 0,1% gewicht per gewicht op artikelniveau:

|  |  |  |
| --- | --- | --- |
| **Productnaam** | **Naan van de stof** | **CAS-nr.** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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Firma GE Healthcare współpracuje ze swoimi dostawcami w celu zagwarantowania zgodności importowanych do Unii Europejskiej lub wytwarzanych na jej obszarze produktów podlegających artykułowi 33 rozporządzenia REACH (rozporządzenie WE nr 1907/2006), które są stosowane w procesie produkcji wyrobów firmy GE Healthcare.

Firma GE Healthcare ma świadomość prawnych zobowiązań wynikających z artykułu 33 rozporządzenia REACH i publikacji listy kandydackiej substancji stanowiących bardzo duże zagrożenie (SVHC), zgodnie z artykułem 59 rozporządzenia REACH, i będzie ich przestrzegać.

Prawidłowo użytkowanych produktów firmy GE Healthcare nie dotyczy zjawisko „zamierzonego uwalniania” substancji.

Z informacji przekazanych nam dotychczas przez naszych dostawców wynika, że wspomniane substancje występują w następujących produktach w stężeniu, które może przekraczać wartość graniczną wynoszącą 0,1% wagi produktu:

|  |  |  |
| --- | --- | --- |
| **Nazwa produktu** | **Nazwa substancji** | **Nr CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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A GE Healthcare trabalha com os seus fornecedores para assegurar a conformidade dos artigos importados ou fabricados dentro da União Europeia sujeitos ao artigo 33.º do regulamento REACH (CE – N.º 1907/2006) e que são utilizados no fabrico de produtos da GE Healthcare.

Relativamente à aplicação do artigo 33.º do regulamento REACH e à publicação da Lista de substâncias que suscitam elevada preocupação (SVHC), de acordo com o artigo 59.º do regulamento REACH, a GE Healthcare tem conhecimento das suas obrigações legais e agirá em conformidade com as mesmas.

Em condições normais de utilização, os artigos da GE Healthcare não "libertam substâncias intencionalmente".

Com as informações dos nossos fornecedores até à data, estas substâncias estão presentes nos seguintes produtos com uma concentração que pode ser superior ao limite de 0,1% de massa por massa ao nível do artigo:

|  |  |  |
| --- | --- | --- |
| **Nome do produto** | **Nome da substância** | **N.º CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare lucrează cu furnizorii săi pentru a asigura conformitatea articolelor importate sau fabricate în Uniunea Europeană care fac obiectul regulamentului REACH (CE-nr. 1907/2006), articolul 33, și care sunt utilizate în producția de produse GE Healthcare.

În ceea ce privește aplicarea articolului 33 din regulamentul REACH și publicarea listei de substanțe care prezintă motive de îngrijorare deosebită (SVHC) în conformitate cu articolul 59 din regulamentul REACH, GE Healthcare are cunoștință de obligațiile legale și le va respecta.

Articolele GE Healthcare nu eliberează în mod intenționat substanțele în condiții normale de utilizare.

Pe baza informațiilor oferite de furnizorii noștri până în prezent, aceste substanțe sunt prezente în următoarele produse într-o concentrație care poate să fie mai mare decât pragul de 0,1% (în greutate) la nivelul articolului:

|  |  |  |
| --- | --- | --- |
| **Numele produsului** | **Denumirea substanței** | **Nr. CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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Spoločnosť GE Healthcare spolupracuje so svojimi dodávateľmi na zabezpečení zhody výrobkov dovážaných alebo vyrábaných v Európskej únii, na ktoré sa vzťahuje nariadenie REACH (ES – č. 1907/2006), článok 33, a ktoré sa používajú pri výrobe produktov GE Healthcare.

Pokiaľ ide o uplatňovanie článku 33 nariadenia REACH a zverejnenie zoznamu navrhovaných látok vzbudzujúcich veľmi veľké obavy (SVHC) podľa článku 59 nariadenia REACH, spoločnosť GE Healthcare si je vedomá svojich zákonných povinností a bude ich dodržiavať.

Produkty GE Healthcare za normálnych podmienok používania „zámerne neuvoľňujú“ látky.

Na základe doterajších informácií od našich dodávateľov sú tieto látky prítomné v nasledujúcich produktoch v koncentrácii, ktorá môže byť vyššia ako prahová hodnota 0,1 % proporcionálnej hmotnosti na úrovni výrobku:

|  |  |  |
| --- | --- | --- |
| **Názov produktu** | **Názov látky** | **Číslo CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare v sodelovanju s svojimi dobavitelji zagotavlja skladnost izdelkov, uvoženih ali proizvedenih v Evropski uniji, za katere velja člen 33 uredbe REACH (št. ES 1907/2006) in ki se uporabljajo pri proizvodnji izdelkov družbe GE Healthcare.

Družba GE Healthcare se zaveda svojih pravnih obveznosti v zvezi z uporabo člena 33 uredbe REACH in objavo seznama kandidatnih snovi, ki vzbujajo veliko skrb (SVHC), v skladu s členom 59 uredbe REACH in bo svoje dolžnosti izpolnjevala.

Izdelki družbe GE Healthcare pod normalnimi pogoji uporabe ne sproščajo snovi "namerno".

Na podlagi dosedanjih informacij naših dobaviteljev so te snovi prisotne v naslednjih proizvodih s koncentracijo, ki je lahko večja od mejne vrednosti 0,1 % teže izdelka na ravni izdelka:

|  |  |  |
| --- | --- | --- |
| **Ime izdelka** | **Ime snovi** | **Št. CAS** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare takaa yhdessä tavarantoimittajiensa kanssa REACH-asetuksen (EY N:o 1907/2006) 33 artiklan alaisten Euroopan unionista tuotujen tai sen alueella valmistettujen sekä GE Healthcaren tuotteiden valmistuksessa käytettyjen tuotteiden säädöstenmukaisuuden.

Koskien REACH-asetuksen 33 artiklan toimeenpanoa ja REACH-asetuksen 59 artiklan mukaisesti julkaistua Ehdokasluetteloa erityistä huolta aiheuttavista aineista (Candidate List of Substances of Very High Concern, SVHC) GE Healthcare tietää lakisääteiset velvollisuutensa ja noudattaa niitä.

GE Healthcaren tuotteista ei tarkoituksellisesti vapaudu aineita normaaleissa käyttöolosuhteissa.

Tavarantoimittajilta näiden tietojen julkaisuajankohtaan mennessä saatujen tietojen perusteella kyseisten aineiden pitoisuus saattaa ylittää 0,1 painoprosentin raja-arvon esinettä kohden seuraavissa tuotteissa:

|  |  |  |
| --- | --- | --- |
| **Tuotteen nimi** | **Aineen nimi** | **CAS-nro** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |

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GE Healthcare samarbetar med sina leverantörer för att säkerställa överensstämmelse för produkter som importeras till eller tillverkas inom EU, omfattas av REACH-förordningen (EG nr. 1907/2006), artikel 33, och används under produktionen av GE Healthcares produkter.

Gällande tillämpningen av artikel 33 i REACH-förordningen och utgivningen av kandidatförteckningen över SVHC-ämnen (Substances of Very High Concern, ämnen som inger mycket stora betänkligheter) i enlighet med artikel 59 i REACH-förordningen är GE Healthcare medvetna om sina juridiska skyldigheter och kommer att leva upp till dem.

GE Healthcares produkter avger inga ”avsiktliga utsläpp” vid normal användning.

GE Healthcares produkter avger inga ”avsiktliga utsläpp” vid normal användning.

Baserat på nuvarande information från våra leverantörer finns de här substanserna i nivåer som kan överskrida tröskelvärdet på 0,1 % vikt/volym i följande produkter:

|  |  |  |
| --- | --- | --- |
| **Produktnamn** | **Ämnets namn** | **CAS-nr** |
| *MLCL ALTIX* | | |
| *ALTIX COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *ALTIX MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v7* | | |
| *v7 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *v7 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *Upgrade Kit MLCL v7.1* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *2451-62-9* |
| *MLCL v6.9.6 R3* | | |
| *v6.9.6 R3 COMBOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 CARDIOLAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |
| *v6.9.6 R3 MAC-LAB* | *Boron oxide (B2O3)*  *Lead*  *Lead oxide (PbO)*  *Silicic acid, lead salt*  *Lead oxide (Pb3O4)*  *1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2-oxiranylmethyl)-* | *1303-86-2*  *7439-92-1*  *1317-36-8*  *11120-22-2*  *1314-41-6*  *2451-62-9* |